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IN THE

Supreme Court of the United States

OCTOBER TERM, 1993

AMERICAN HOME PRODUCTS CORPORATION and QUANTUM PHARMICS, LTD.,

Petitioners,

vs.

MYLAN LABORATORIES, INC., et al.,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

Of Counsel:
WILLIAM J. RUANE
AMERICAN HOME PRODUCTS CORPORATION
Madison, New Jersey

ARNOLD & PORTER
New York, New York
and Washington, D.C.

PETER L. ZIMROTH
Counsel of Record
KENNETH V. HANDAL
ROSEMARY Q. BARRY
399 Park Avenue
New York, New York 10022
(212) 715-1000

STUART J. LAND
THOMAS J. MCGREW
1200 New Hampshire Avenue, N.W.
Washington, D.C. 20036
(202) 872-6700

Attorneys for Petitioners American Home Products Corporation and Quantum Pharmics, Ltd.

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QUESTION PRESENTED

The question presented is whether, in reviewing the district court's denial of leave to amend under Federal Rule of Civil Procedure 15(a), the court of appeals should have applied an abuse of discretion standard rather than reviewing the decision de novo.

PARTIES TO THE PROCEEDINGS

The plaintiff in the district court was Mylan Laboratories, Inc. The plaintiff below was also the appellant in the court of appeals and is a respondent here. The defendants in the district court were seven corporations (Pharmaceutical Basics, Inc., Par Pharmaceutical, Inc., Quad Pharmaceuticals, Inc., American Therapeutics, Inc., Vitarine Pharmaceuticals, Inc., American Home Products Corporation and Quantum Pharmics, Ltd.) and twelve individuals (Raj Matkari, Ashok Patel, Dilip Shah, Raju Vegesna, Mohammed Azeem, Steven Colton, Jin-Shung Chang, Charles Chang, David Brancato, Walter Kletch, Jan T. Sturm and Salvatore J. Pinella). With the exception of Vitarine Pharmaceuticals, Inc. and Ashok Patel,

all of the defendants below were also appellees in the court of appeals.

The present petitioners, American Home Products Corporation and Quantum Pharmics, Ltd., were two of the appellees in the court of appeals. The other appellees are respondents here.

RULE 29.1 STATEMENT

Petitioner American Home Products Corporation has no parent company. American Home Products Corporation has no subsidiaries that are not wholly owned, but does hold a 67% equity interest in Genetics Institute, Inc.

The parent company of petitioner Quantum Pharmics, Ltd. is American Home Products Corporation. Quantum Pharmics, Ltd. has no subsidiaries.

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Respondents.

Petition for a Writ of Certiorari

to the United States Court of Appeals

for the Fourth Circuit

PETITION FOR WRIT OF CERTIORARI

American Home Products Corporation ("AHP") and Quantum Pharmics, Ltd. ("Quantum") respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Fourth Circuit.

OPINIONS BELOW

The opinion of the court of appeals is reported at 7 F.3d 1130 (4th Cir. 1993) and reproduced in the Appendix ("App.") at pages 1a to 46a. The court of appeals' denial of rehearing and rehearing in banc (App. at 117a-119a) has not been reported. The opinion of the district court (App. at 47a-116a) is reported at 808 F. Supp. 446 (D. Md. 1992).

JURISDICTION

The judgment of the court of appeals was entered on October 18, 1993 (App. at 1a-2a), and timely petitions for rehearing were denied on November 16,

1993 (App. at 117a-119a). The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1) (1988).

RULE INVOLVED

Rule 15(a) of the Federal Rules of Civil Procedure provides:

> Rule 15. Amended and Supplemental Pleadings
>
> (a) Amendments. A party may amend the party's pleading once as a matter of course at any time before a responsive pleading is served or, if the pleading is one to which no responsive pleading is permitted and the action has not been placed upon the trial calendar, the party may so amend it at any time within 20 days after it is served. Otherwise a party may amend the party's pleading only by leave of court or by written consent of the adverse party; and leave shall be freely given when justice so requires. A party shall plead in response to an amended pleading within the time remaining for response to the original pleading or within 10 days after service of the amended pleading, whichever period may be the longer, unless the court otherwise orders.

STATEMENT

This case presents an important question under the Federal Rules of Civil Procedure. At issue is the extent to which district courts are able to control the conduct of litigants before them. The district court dismissed plaintiff's Third Amended Complaint and then, exercising its discretion, refused to permit the filing of any further amended complaints. The district court's decision was based on a long history of dilatory behavior and the fact that plaintiff's most recent amended complaint contained the same fundamental defect that had caused the district court to dismiss a prior amended complaint. Plaintiff Mylan Laboratories, Inc. ("Mylan") had persisted, in the face of a prior contrary ruling, in basing its Third Amended Complaint on the theory (unsupported by any factual allegations)

that all the unrelated defendants had engaged in a global conspiracy and a single "pattern of racketeering activity" under RICO. This theory, which permeated every pleading filed by Mylan in this action, was part of its attempt to tar every defendant with the alleged wrongdoing of every other defendant.

The Court of Appeals for the Fourth Circuit agreed with the district court that the Third Amended Complaint was based on the same theory -- the existence of a single pattern of activity -- that had previously been rejected and agreed also that such a theory was not supportable. Nevertheless, the court of appeals reversed the district court's dismissal with prejudice and granted Mylan yet another chance to replead. In doing so, the court of appeals ignored the long history of dilatory behavior that had been before the district court

and refused to review the district court's decision for an abuse of discretion. Instead, the court of appeals granted permission to replead as if that question were before it to decide de novo.

In applying the wrong standard of review, the Fourth Circuit has put itself in conflict with the decisions of this Court and of every other circuit and has severely restricted the ability of the district courts in the Fourth Circuit to control the behavior of litigants before them.

A. Proceedings in the District Court

Respondent Mylan is a manufacturer of generic and innovator drugs. Its Third Amended Complaint alleged that, in order to harm Mylan, nineteen defendants had participated in one common pattern of racketeering activity designed to corrupt the Food and Drug Administration's

("FDA") procedures for approving generic drugs.[1] That complaint named as defendants six corporations that manufactured generic drugs, including petitioner Quantum, and twelve individuals. Petitioner AHP was also named as a defendant but did not manufacture any of the drugs at issue and was named solely because it was Quantum's parent.

By the time Mylan's Third Amended Complaint was dismissed with prejudice, the district court had had before it four different versions of Mylan's complaint.

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[1] The jurisdiction of the district court was invoked under: 18 U.S.C. § 1964 (jurisdiction over RICO claims asserted under 18 U.S.C. § 1962); 15 U.S.C. § 1121 (jurisdiction over Lanham Act claims asserted under 15 U.S.C. § 1125); 28 U.S.C. § 1331 (general federal question jurisdiction); and 28 U.S.C. § 1332 (diversity jurisdiction).

Three separate judges found not only serious defects in the pleadings but also serious improprieties in Mylan's prosecution of this case. Those judges had chastised Mylan: (a) for initially filing the action in a venue that was "clear[ly] . . . improper," Mylan Laboratories, Inc. v. Akzo, N.V., 1990-1 Trade Cas. (CCH) ¶ 69,981 at 63,309 (D.D.C. 1990); (b) for defending its choice of venue with assertions that were "close to misleading," id. at 63,317; (c) for filing an "'inherently implausible'" conspiracy claim in a generic drug industry that was intensely competitive, Mylan Laboratories, Inc. v. Akzo, N.V., 770 F. Supp. 1053, 1068 (D. Md. 1991); (d) for making assertions unsupported by the record and impermissibly attempting to amend pleadings with "irrelevant" and "unavailing" and "inappropriate" post-hoc allegations in its legal memoranda, App.

at 63a-64a & n.5; 808 F. Supp. at 451 & n.5; (e) for repeatedly violating the court's rules as well as explicit directions from the court in a manner that was "astounding," App. at 58a; 808 F. Supp. at 449, and which "confused [the record] virtually beyond analysis," Mylan Laboratories, Inc. v. Akzo, N.V., No. R-90-1096, slip op. at 3 (D. Md. May 19, 1992); and (f) for making belated requests for discovery designed "to delay [the case] and keep [it] going on forever," Transcript of Hearing on Akzo's Motion to Dismiss at 26, Mylan Laboratories, Inc. v. Akzo, N.V., No. R-90-1096 (D. Md. June 19, 1992).

As the district court said, all this had caused the case to "languish[ ] in procedural limbo for years," App. at 71a, 113a; 808 F. Supp. at 452, 461, amounted to an affront to the district court and resulted in severe prejudice to AHP and

Quantum. For almost three years, they had been branded as "racketeers" based on defective and improper legal and factual theories.

Finally, Judge Smalkin, the third district judge to handle the case, had enough. He dismissed the complaint with prejudice. He did so based on the history of abusive practices by Mylan and after clear warnings. And he did so because, in spite of a prior ruling to the contrary, Mylan persisted in basing its most recent complaint on an impermissible theory that linked all the unrelated defendants together without any basis and attributed to each the alleged wrongdoing of the others.

1. The First Complaint

Mylan filed its first complaint in this action more than four and a half years ago (June 8, 1989), in the United States District Court for the District of

Columbia. That complaint, a prolix 213-page affair, alleged 34 antitrust and two RICO counts against seven individuals and six corporations that allegedly banded together to corrupt the FDA in order to harm Mylan. Complaint in Mylan Laboratories, Inc. v. Akzo, N.V., No. 89-1671 (D.D.C., dated June 8, 1989). That complaint did not name or mention either AHP or Quantum.

On March 27, 1990, the court (Hon. Thomas F. Hogan) found that venue was "clear[ly]" improper in the District of Columbia and ordered the case transferred to the District of Maryland, where the FDA is located. Mylan Laboratories Inc. v. Akzo, N.V., 1990-1 Trade Cas. (CCH) ¶ 69,981 at 63,309 (D.D.C. 1990). Judge Hogan was "at a loss" to understand why Mylan brought the case in the District of Columbia "except, perhaps, for the fact that plaintiff's attorneys are located

here." Id. at 63,317. Judge Hogan found Mylan's assertions concerning where the controversy arose to be "close to misleading." Id.

2. The First Amended Complaint

On June 27, 1990, three months after Judge Hogan's ruling, Mylan moved for leave to file an amended and supplemental complaint. On July 26, 1990, the Honorable Norman Ramsey, the United States District Judge for the District of Maryland to whom the case had been transferred, granted that motion. Mylan Laboratories, Inc. v. Akzo, No. R-90-1096 (D. Md. July 26, 1990) (order granting leave to amend). Mylan's second attempt at a complaint was 255 pages long and added for the first time the afterthought that Quantum, too, was part of a large scheme to corrupt the FDA. First Amended Complaint of Plaintiff Mylan Laboratories, Inc., dated June 27, 1990.

The First Amended Complaint also added AHP as a defendant solely on the basis that it was Quantum's parent. Not a single allegation of wrongful conduct was made against AHP.

Mylan's First Amended Complaint alleged 37 antitrust counts, three RICO counts and one state law count alleging unfair competition. As with Mylan's original complaint, the core of the First Amended Complaint was Mylan's assertion that each defendant could be held liable for the alleged wrongdoing of the others under a "global" conspiracy theory that all defendants joined together in a common goal to corrupt the FDA in order to harm Mylan. E.g., First Amended Complaint at 37-76, 79-87.

3. Dismissal of Most of the First Amended Complaint

In a Memorandum and Order dated August 15, 1991, Judge Ramsey dismissed

most of the First Amended Complaint against most of the defendants. Mylan Laboratories, Inc. v. Akzo, N.V., 770 F. Supp. 1053 (D. Md. 1991).

The court dismissed Mylan's "global" antitrust and RICO conspiracy claims on the ground that Mylan's claim of a conspiracy among the 19 defendants was unsupported by any factual allegations in the complaint. Judge Ramsey further found Mylan's claim "'inherently implausible'" with respect to a generic industry that, according to the First Amended Complaint itself, was "intensely competitive." Id. at 1068. Mylan apparently recognized the absence of any factual allegations of joint activity in its complaint and attempted to cure this defect by making unsupported allegations in its legal memoranda. Judge Ramsey rejected this attempt and admonished

Mylan that he would not consider the extra-complaint allegations. Id.

For the same reasons that he rejected Mylan's allegation of a "global" conspiracy, Judge Ramsey also rejected -- explicitly -- Mylan's attempt in the substantive RICO counts to charge a single "pattern of racketeering activity," thereby attributing the alleged wrongdoing of each defendant to all the others. Id. at 1077. Judge Ramsey dismissed all the RICO claims against Quantum and Quantum's parent, AHP, id. at 1078; and he dismissed Mylan's thirty-seven antitrust counts in their entirety, id. at 1062-68 & nn.8-9.

In the course of his opinion, Judge Ramsey made rulings about what could be included in Mylan's next amended complaint. He analyzed each of the predicate acts charged and opined which could and which could not withstand legal

challenge. Id. at 1069-1084. He also made it clear that these predicate acts could not be charged as part of one pattern of activity in which all the defendants participated. Id. at 1077.

4. The Second Amended Complaint

Although it had been given an opportunity to replead its case once again, Mylan did nothing for almost seven months. Finally, on March 9, 1992, Mylan moved for yet a third chance to file a complaint in this action. Mylan claimed that a third chance was warranted by the "discovery of new facts," Memorandum of Plaintiff Mylan Laboratories, Inc. in Support of Its Motion for Leave to Amend, Supplement and Add a New Party to Its Complaint, dated March 9, 1992, at 2, many of which it had access to for years. See Second Amended Complaint of Plaintiff Mylan Laboratories, Inc., dated March 9, 1992, at ¶¶ 119(b)-(d).

Mylan also asserted for the first time Lanham Act claims against several defendants. The new Lanham Act claim against AHP and Quantum was based on facts of which Mylan had notice almost two years before and could have been included in the First Amended Complaint. See Second Amended Complaint at ¶¶ 100, 102-103. In its Second Amended Complaint, without any explanation, Mylan also changed the products as to which it claimed to have been harmed, dropping one third of them from the last complaint and adding new ones. Compare First Amended Complaint, ¶¶ 75-97 with Second Amended Complaint, ¶¶ 81-96.

5. The Denial of Mylan's Motion to File the Second Amended Complaint

In seeking leave to file a Second Amended Complaint, Mylan promised that the new complaint "conform[ed]" to Judge Ramsey's August 1991 opinion by, inter

alia, deleting the antitrust counts, the RICO conspiracy claim, and "all other references to a global conspiracy." Memorandum of Plaintiff Mylan Laboratories, Inc. in Support of Its Motion For Leave to Amend, Supplement and Add a New Party to Its Complaint, dated March 9, 1992, at 1-2.

However, while making this promise, Mylan was making it almost impossible to judge whether the promise had been fulfilled. The Second Amended Complaint did not comply with Maryland District Court Rule 103(6)(c), which requires amendments to be highlighted. Thus, on May 19, 1992, Judge Ramsey denied Mylan's motion for leave to amend. Mylan Laboratories, Inc. v. Akzo, N.V., No. R-90-1096, slip op. at 4 (D. Md. May 19, 1992). He said that because of Mylan's failure to follow the court's rule, the record had become "confused virtually

beyond analysis by the proposed second amended complaint," and that it was "almost impossible" to determine "whether the new complaint in fact conforms to the Court's earlier opinion." Id. at 3. Nonetheless, Judge Ramsey gave Mylan yet another chance to submit a complaint that conformed to the court's rules. Id. at 4.

6. Mylan's Motion to File Third Amended Complaint

On June 11, 1992, Mylan submitted a highlighted Second Amended Complaint and a revised motion to amend. Soon after Judge Ramsey announced his retirement on June 19, 1992, the case was transferred to the Honorable Frederic Smalkin. On July 8, 1992, Judge Smalkin granted Mylan's revised motion to amend, except as to one defendant that had been dismissed in the interim. Mylan

Laboratories, Inc. v. Akzo, No. S-90-1096, slip op. at 5 (D. Md. July 8, 1992).

Having had an opportunity to review the history of the matter and, in an effort "to prevent this case from becoming totally unmanageable," Judge Smalkin warned Mylan that "this opinion will end the question of complaint amendment in this lawsuit, and no further motions to amend pleadings will be entertained." Id. at 2 (emphasis by the court).

7. The Third Amended Complaint

On July 23, 1992, Mylan filed a Third Amended Complaint and a highlighted version of the Third Amended Complaint. Mylan represented that it had made "no substantive change[s]" when excising the references in that complaint to the defendant that had been dismissed. Resubmission of Amended Complaint by

Plaintiff Mylan Laboratories, Inc., dated July 23, 1992, at 2. In fact, as the district court later found, Mylan had made substantive changes; and those changes were not highlighted as required by the local rule. App. at 57a-58a; 808 F. Supp. at 449.

More significantly, in the Third Amended Complaint, Mylan ignored Judge Ramsey's rulings about how to frame its amended complaint. It reasserted the same theory of joint activity and common purpose among the defendants that Judge Ramsey had previously found to be deficient. Without any supporting factual allegations, Mylan once again alleged a single "pattern of racketeering" activity in which all the defendants allegedly participated. E.g., Third Amended Complaint of Plaintiff Mylan Laboratories, Inc., dated July 23, 1992, at ¶¶ 113-121, 128, 132, 134.

The Third Amended Complaint alleged four counts against 19 defendants. Count One alleged a RICO claim under 18 U.S.C. § 1962(c) (conducting the affairs of a racketeering enterprise). Count Two asserted a RICO claim under 18 U.S.C. § 1962(a) (receiving income from a pattern of racketeering). Count Three was Mylan's new Lanham Act claim under 15 U.S.C. § 1125. Count Four, Mylan's state claim for unfair competition and malicious interference with business relations, simply incorporated by reference the allegations of Counts One and Two.

8. The District Court's Decision Dismissing the Third Amended Complaint with Prejudice

On December 8, 1992, Judge Smalkin dismissed Mylan's Third Amended Complaint with prejudice. In his opinion, Judge Smalkin rebuked Mylan for its "cavalier attitude" towards its own repeated

disregard of court rules. App. at 57a-58a; 808 F. Supp. at 449. He found that, once again, Mylan's complaint (Counts One, Two and Four) was based on the same theory of global conspiracy previously rejected by Judge Ramsey. App. at 63a, 68a-69a; 808 F. Supp. at 450-452. Once again, without any supporting factual allegations, Mylan alleged a single "pattern of racketeering" activity in which all the defendants participated. App. at 63a; 808 F. Supp. at 450-51. Judge Smalkin agreed with Judge Ramsey's earlier conclusion that such a claim had no factual support in the complaint. App. at 61a & n.4, 68a-69a; 808 F. Supp. at 450-52 & n.4. Because Judge Smalkin found that "Mylan [could] prove no set of facts which support its claim" that there was a single pattern of activity, and because Counts One, Two and Four were based upon that claim, he dismissed those

counts. App. at 71a-72a; 808 F. Supp. at 452.

The question then before Judge Smalkin was whether Mylan should be permitted to amend its complaint yet again to state separate claims for separate patterns of racketeering activity. In view of Mylan's dilatory behavior, its repeated attempts to file defective complaints, its ignoring rules of court and prior court rulings, Judge Smalkin decided that he could not "permit yet another amendment, simply in order to allow Mylan one more opportunity to rectify its flawed complaint." App. at 70a-71a; 808 F. Supp. at 452. Nor did Judge Smalkin believe it appropriate to do again what Judge Ramsey had done once without effect -- that is, parse Mylan's complaint to see whether there was some way to save it by decomposing the single pattern of racketeering alleged into

several separate patterns. "So to do would be, in essence, to write the complaint for the plaintiff." App. at 71a; 808 F. Supp. at 452. Noting that "[n]othing in the current round of motions has served to change the Court's position" that there should be no further amendments, Judge Smalkin concluded that this litigation -- having "languished in procedural limbo for years" -- "ha[d] gone far enough." App. at 71a, 113a-114a; 808 F. Supp. at 452, 461.[2]

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[2] With respect to Count Three, the district court dismissed without further leave to amend because Mylan had failed to plead an essential element of a Lanham Act claim and because it conceded that it might be able to make the missing allegation only after discovery. App. at 106a-113a; 808 F. Supp. at 459-461. In light of the history of dilatory behavior, the fact that Mylan had had several prior opportunities to amend its complaint, and the fact that it had been warned that there could be no further amendments, the district court declined to permit any further proceedings. App. at 113a-114a; 808 F. Supp. at 461.

B. The Court of Appeals Opinion

On appeal, the Fourth Circuit agreed that the claim of a single pattern of racketeering activity was the core (the "'theme'") of Counts One, Two and Four of the complaint. App. at 17a; 7 F.3d at 1134. The court also agreed that "[t]he district court and the defendants have convincingly demonstrated that not one of the extensive allegations described in Mylan's complaint supports any claim that all of the defendants acted together, in a single, global pattern of racketeering activity, driven by the united goal of profiting illegally at Mylan's expense." App. at 17a-18a (emphasis by the court); 7 F.3d at 1134. Thus, the Fourth Circuit agreed with the district court's conclusion that Mylan could not proceed on the basis of the Third Amended Complaint (Counts One, Two and Four) as

pleaded. App. at 17a-18a, 26a; 7 F.3d at 1134, 1136.

The court of appeals did not then review for an abuse of discretion the district court's refusal to grant further leave to amend. See App. at 43a; 7 F.3d at 1139. Instead, the court of appeals proceeded as if the question were one for de novo review. The court said it could "glean[]" from the Third Amended Complaint several separate patterns of racketeering activities which, if pleaded as separate patterns against individual groups of defendants, could state causes of action. App. at 20a; 7 F.3d at 1135. The district court erred, said the court of appeals, by "overlook[ing] the viability" of Counts One, Two and Four "independent of any global action" actually pleaded in those counts. App. at 20a-21a; 7 F.3d at 1135. Accordingly, the court of appeals reversed and

remanded so that Mylan could amend its pleading once again.

REASONS FOR GRANTING THE WRIT

Review by this Court of the court of appeals' decision is warranted for two reasons. First, the Fourth Circuit's refusal to review for an abuse of discretion the district court's denial of leave to amend conflicts with decisions of this Court and of every other circuit. Second, the court of appeals' application of a de novo standard of review undermines the authority of district judges to control their dockets and govern the conduct of litigants before them. This threat to the authority of the district court, we respectfully submit, calls for the exercise of this Court's supervisory power.

The Standard of Review Applied by the Fourth Circuit Conflicts with Decisions of This Court and Every Other Federal Court of Appeals and Undermines the Authority of the District Court

The court of appeals reversed and remanded for further proceedings because, it said, the district court "overlooked the viability of [Counts One, Two and Four of the Third Amended Complaint] independent of [the] global action" actually pleaded in those counts. App. at 20a-21a; 7 F.3d at 1135. The district court did not, however, overlook this issue. On a prior occasion the district court (Judge Ramsey) had ruled on the viability of Mylan's earlier complaint independent of the global action pleaded there. Mylan Laboratories, Inc. v. Akzo, N.V., 770 F. Supp. 1053, 1077-78 (D. Md. 1991). Judge Smalkin believed there was no reason for him to go through the same exercise again. The question before

Judge Smalkin was not whether, if given another chance, Mylan was capable of pleading a viable complaint. The question was whether, under Federal Rule of Civil Procedure 15(a), Mylan should be given another chance.

On this question the district court exercised its discretion and decided that plaintiff had had enough chances. That decision was based on the facts that Mylan had already made several unsuccessful attempts to file proper pleadings, that it ignored a prior ruling of the court which had given instructions on how to plead, and that it had engaged in several other varieties of dilatory behavior (see pages 6-25 supra). Judge Smalkin simply did not think it appropriate to hunt through the Third Amended Complaint in search of viable theories that might have been pleaded, but were not.

The district court's exercise of discretion is, of course, reviewable by the court of appeals but only for an abuse of discretion. That has been the ruling of this Court and of every federal court of appeals, except now the Fourth Circuit. See Zenith Radio Corp. v. Hazeltine Research, Inc., 401 U.S. 321, 330 (1971); Foman v. Davis, 371 U.S. 178, 182 (1962); Hayduk v. Lanna, 775 F.2d 441, 445 (1st Cir. 1985); Mooney v. Vitolo, 435 F.2d 838, 839 (2d Cir. 1970) (per curiam); Skehan v. Bd. of Trustees of Bloomsburg State College, 590 F.2d 470, 492 (3d Cir. 1978), cert. denied, 444 U.S. 832 (1979); Smith v. Ayres, 845 F.2d 1360, 1366 (5th Cir. 1988); Banque de Depots v. National Bank of Detroit, 491 F.2d 753, 757 (6th Cir. 1974); Midwest Grinding Co. v. Spitz, 976 F.2d 1016, 1020-21 (7th Cir. 1992); Izaak Walton League of America v. St. Clair,

497 F.2d 849, 854 (8th Cir.), cert. denied, 419 U.S. 1009 (1974); Allen v. City of Beverly Hills, 911 F.2d 367, 373-74 (9th Cir. 1990); Woolsey v. Marion Laboratories, Inc., 934 F.2d 1452, 1462 (10th Cir. 1991); National Distillers and Chemical Corp. v. Brad's Machine Products, 666 F.2d 492, 497 (11th Cir. 1982); Doe v. McMillan, 566 F.2d 713, 720 (D.C. Cir. 1977), cert. denied, 435 U.S. 969 (1978); Tenneco Resins, Inc. v. Reeves Bros., Inc., 752 F.2d 630, 633 (Fed. Cir. 1985); 3 J. William Moore & Richard D. Freer, Moore's Federal Practice, ¶ 15.10 at 15-106 (2d ed. 1993).

The point of this rule is to ensure that the district court has sufficient ability to control the conduct of litigants before it. This authority is essential if district courts are to have any hope of meeting the challenge of

growing dockets. In an analogous context, this Court explained why it is important for the district court to have broad discretion to dismiss complaints with prejudice in order to deter conduct that interferes with proper proceedings. National Hockey League v. Metropolitan Hockey League, 427 U.S. 639, 642 (1976) (per curiam). In National Hockey League, without argument, the Court granted a petition for writ of certiorari and summarily reversed the court of appeals, reinstating the district court's dismissal of the action with prejudice under Rule 37 of the Federal Rules of Civil Procedure (for failure to answer interrogatories timely). As this Court said:

> The question, of course, is not whether this Court, or whether the Court of Appeals, would as an original matter have dismissed the action; it is whether the District Court abused its discretion in so doing.

Id. The court of appeals' judgment, the Court said, "cannot be allowed to wholly supplant other and equally necessary considerations embodied in [the] Rule." Id.

It is extremely unlikely that had the court of appeals applied the proper standard of review, it would have ruled as it did. Finding an abuse of discretion in the circumstances of this case would itself have been contrary to the rulings of several other courts of appeals which have considered cases similar to this one. See, e.g., Hayduk v. Lanna, 775 F.2d 441, 445 (1st Cir. 1985) (denial of leave to amend and dismissal with prejudice "was well within the discretion of the district court especially since the plaintiffs were notified before amending a second time" of the deficiencies of the complaint and failed to correct them); Mooney v.

Vitolo, 435 F.2d 838, 839 (2d Cir. 1970) (per curiam) (within sound discretion to deny leave to make third attempt to replead); Smith v. Ayres, 845 F.2d 1360, 1366 (5th Cir. 1988) (denial of leave to amend proper where plaintiff had repeatedly failed to remedy deficiencies in his earlier complaints); Midwest Grinding Co. v. Spitz, 976 F.2d 1016, 1020-21 (7th Cir. 1992) (denial of "leave to file a third amended complaint is firmly within [district court's] discretion," especially when plaintiff "had fair notice of its pleading deficiencies . . . , but it chose to ignore that warning"); Allen v. City of Beverly Hills, 911 F.2d 367, 373-74 (9th Cir. 1990) (repeated failure to cure pleading deficiencies was a sufficient basis for affirming denial of leave to file fourth complaint and dismissal with prejudice).

CONCLUSION

This petition for a writ of certiorari should be granted.

Respectfully submitted,

Of Counsel:
WILLIAM J. RUANE
American Home
Products Corporation
Madison, New Jersey

ARNOLD & PORTER
New York, New York
and Washington, D.C.

PETER L. ZIMROTH
Counsel of Record
KENNETH V. HANDAL
ROSEMARY Q. BARRY
399 Park Avenue
New York, New York
10022
(212) 715-1000

STUART J. LAND
THOMAS J. MCGREW
1200 New Hampshire
Avenue, N.W.
Washington, D.C.
20036
(202) 872-6700

Attorneys for
Petitioners
American Home
Products
Corporation and
Quantum
Pharmics, Ltd.

February 4, 1994

APPENDICES

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

Mylan Laboratories, Incorporated, Plaintiff-Appellant, v. Raj Matkari; Dilip Shah; Raju Vegesna; Mohammed F. Azeem; Charles Chang; David J. Brancato; Jin-Shung Chang; Walter Kletch; Jan T. Sturm; Pharmaceutical Basics, Incorporated; Par Pharmaceuticals, Incorporated; Quad Pharmaceuticals, Incorporated; American Therapeutics, Incorporated; American Home Products Corporation; Quantum Pharmics, Limited; Steven Colton; Salvatore J. Pinella, Defendants-Appellees, and Ashok Patel; Vitarine Pharmaceuticals, Incorporated; Defendants.	No. 93-1041

Appeal from the
United States District Court for
the District of Maryland, at Baltimore.
Frederic N. Smalkin, District Judge.
(CA-90-1096-S)

Argued: May 3, 1993

Decided: October 18, 1993

Before ERVIN, Chief Judge, and
MURNAGHAN and
NIEMEYER, Circuit Judges.

Reversed by published opinion.
Judge Murnaghan wrote the opinion, in
which Chief Judge Ervin and Judge
Niemeyer joined.

COUNSEL

ARGUED: Judah Best, DEBEVOISE & PLIMPTON, Washington, D.C., for Appellant. Peter Zimroth, ARNOLD & PORTER, New York, New York; Donald John Mulvihill, CAHILL, GORDON & REINDEL, Washington, D.C., for Appellees. **ON BRIEF:** Loren Kieve, Ann M. Ashton, DEBEVOISE & PLIMPTON, Washington, D.C., for Appellant. Walter Kletch, Jan T. Sturm, Appellees. Kenneth V. Handal, ARNOLD & PORTER, New York, New York; Kathy Silberthau Strom, Scott A. Martin, CAHILL, GORDON & REINDEL, Washington, D.C.; William J. Ruane, Assistant General Counsel-Litigation, AMERICAN HOME PRODUCTS CORPORATION, New York, New York; Thomas J. McGrew, Washington, D.C.; Richard M. Cooper, Richard S. Hoffman,

David C. Kiernan, WILLIAMS & CONNOLLY, Washington, D.C.; Steven Salky, ZUCKERMAN, SPAEDER, GOLDSTEIN, TAYLOR & KOLKER, Washington, D.C.; Hamilton P. Fox, III, SUTHERLAND, ASBILL & BRENNAN, Washington, D.C.; August Draeb, DRAEB LAW OFFICE, Hebron, North Dakota, for Appellees.

OPINION

MURNAGHAN, Circuit Judge:

Plaintiff-appellant Mylan Laboratories, Inc. ("Mylan") has appealed the dismissal of its Third Amended Complaint for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). The district court dismissed all of Mylan's claims with prejudice.

On appeal, Mylan has maintained that its Third Amended Complaint was sufficient to survive the Rule 12(b)(6) stage. Specifically, Mylan has asserted that it properly alleged numerous violations of the Racketeer Influenced

and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 et seq., several claims for damages for false advertising under the Lanham Act, 15 U.S.C. §§ 1117 and 1125(a), and, finally, state law claims for unfair business competition and tortious interference with prospective business relations. Mylan further has contended that even if it failed to state a claim under Rule 12(b)(6), the district court abused its discretion when it dismissed the complaint with prejudice and prohibited further motions to amend.

Mylan is a corporation engaged in developing, manufacturing, and distributing prescription and generic drugs. In 1989, it filed suit against several manufacturers involved either directly or through a subsidiary in the generic drug industry, various officers of those corporations, and several employees of the Food and Drug

Administration ("FDA"). Mylan originally filed its suit in the United States District Court for the District of Columbia; however, in March 1990, Judge Thomas F. Hogan, finding venue to be improper, transferred the case to the District of Maryland. Shortly thereafter, Mylan completed its first round of amendments to its complaint. The First Amended Complaint charged the defendants with numerous anti-trust violations, violations of RICO, and violations of state law for unfair business competition and tortious interference with prospective business relations. Mylan essentially claimed that between 1984 and 1989, the defendants conspired to facilitate and did facilitate fraudulent FDA approval of their abbreviated new drug applications

("ANDAs") for generic drugs.[1] At the same time, the complaint charged, the defendants wrongfully delayed or impeded the processing of Mylan's ANDAs.

Upon review of a motion to dismiss the First Amended Complaint, Judge Norman P. Ramsey of the United States District Court for the District of Maryland dismissed against all of the defendants Mylan's anti-trust claims and Count 3, a RICO claim premised on a theory of a single conspiracy or joint action among all of the defendants in violation of 18 U.S.C. § 1962(d). In ruling on the legal sufficiency of the remaining RICO counts,

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[1] No generic drug may be marketed without FDA approval of an ANDA. The approval process for ANDAs is designed to occur on a "first-in, first-out basis, 'i.e., the first ANDA submitted to the FDA which satisfactorily passed the labeling, bioequivalency, and chemistry reviews would receive the first approval for a particular generic drug.'" Mylan Lab., Inc. v. Akzo, N.V., 770 F. Supp. 1053 (D. Md. 1991).

Judge Ramsey considered Mylan's pleadings of predicate acts, which included allegations of bribery, obstruction of justice, and mail and wire fraud. He concluded that one of Mylan's theories of mail and wire fraud was legally insufficient and that the other was not pleaded with enough particularity under Federal Rule of Civil Procedure 9(b). Judge Ramsey then dismissed Count 1, arising under RICO, 18 U.S.C. § 1962(c), against only American Home Products Corp. ("AHP"), Quantum Pharmics, Ltd. ("Quantum"), and Jin-Shung Chang on the grounds that Mylan had failed to show a pattern of racketeering activity. He also dismissed Count 2, arising under RICO, 18 U.S.C. § 1962(a), against individual defendants Raj Matkari, Ashok Patel, Dilip Shah, Raju Vegesna, as well as against Jin-Shung Chang and corporate defendants AHP and Quantum. Judge Ramsey

completed his review by sustaining, as against all of the defendants, Mylan's state-law claims. See Mylan Lab., Inc. v. Akzo, N.V., 770 F. Supp. 1053 (D. Md. 1991).

Mylan then moved to file a Second Amended Complaint. The new complaint contained substantial alterations, including additions of new claims and new allegations, as well as numerous deletions. Judge Ramsey, however, denied without prejudice Mylan's motion to amend on the grounds that Mylan had failed to comply with Local Rule 103.6.c which requires highlighting of all amendments. The record, the Judge noted in his ruling, had become "confused virtually beyond analysis by the proposed second amended complaint." In short, the highlighting of all changes to the complaint was essential for the case to proceed properly. Mylan promptly

submitted a corrected complaint and a revised Motion to Amend.

Shortly thereafter, Judge Ramsey left the bench, and the case was transferred to Judge Frederic N. Smalkin of the United States District Court for the District of Maryland. Before granting Mylan's revised motion to amend, Judge Smalkin ordered Mylan to delete all claims against corporate defendant Akzo, N.V., in accordance with Judge Ramsey's then-recent ruling dismissing the corporation from the case for lack of personal jurisdiction. See Mylan Lab., Inc. v. Akzo, N.V., No. 92-1826 (4th Cir. Aug. 6, 1993) (affirming Judge Ramsey). Finally, in order "to prevent this case from becoming totally unmanageable," Judge Smalkin announced that he would permit no further motions to amend after Mylan's resubmission. In July 1992,

Mylan submitted its Third Amended Complaint.

The most recent and substantially down-sized complaint contains four counts. The complaint lists as defendants seven corporations: Pharmaceutical Basics, Inc. ("PBI"), Par Pharmaceutical, Inc. ("PAR"), a Par subsidiary, Quad Pharmaceuticals, Inc. ("Quad"), American Therapeutics, Inc. ("ATI"), Vitarine Pharmaceuticals, Inc. ("Vitarine"), Quantum, and Quantum's parent, AHP. In addition, the complaint lists various individual defendants, including persons who are or were at all relevant times officers of the defendant corporations or FDA employees. Counts 1 and 2 assert violations of RICO essentially consonant with those Judge Ramsey had ruled in favor of allowing to proceed. Specifically, Count 1 alleges a violation by all defendants of 18 U.S.C.

§ 1962(c).[2] Count 2 alleges that defendants PBI, Par, Quad, ATI, Vitarine, AHP, Quantum, Mohammed Azeem, Jin-Shung Chang, Charles Chang, David Brancato, Walter Kletch, and Jan T. Sturm violated

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[2] Section 1962(c) states:

> It shall be unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt.

18 U.S.C. § 1962(a).[3] In Count 3, Mylan introduced a claim that had not appeared in the First Amended Complaint and, hence, had not been addressed by Judge Ramsey. The new allegations state that defendants AHP, Quantum, PBI, and Par violated the Lanham Act, 15 U.S.C. § 1125(a), by using false and misleading advertisements. Finally, Count 4

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[3] Section 1962(a) states in pertinent part:

> It shall be unlawful for any person who has received any income derived, directly or indirectly, from a pattern of racketeering activity or through collection of an unlawful debt in which such person has participated as a principal within the meaning of section 2, title 18, United States Code, to use or invest, directly or indirectly, any part of such income, or the proceeds of such income, in acquisition of any interest in, or the establishment or operation of, any enterprise which is engaged in, or the activities of which affect, interstate or foreign commerce . . . .

reasserts against all of the defendants the state-law claims of unfair business competition and tortious interference with business relations.

With respect to Counts 1 and 2 (the RICO counts) and Count 4 (the state law claim), it is true that Mylan has kept in its Third Amended Complaint general language that suggests some claim of a joint or "global" conspiracy among all of the defendants to commit a single pattern of racketeering activity. Judge Ramsey already had ruled, and Judge Smalkin agreed, that a claim of a global action among all of the defendants was not supported by Mylan's allegations. Perhaps the global conspiracy language which remains in the third version of the complaint was the result of less-than-careful draftsmanship. The language also could be read as a highly simplistic and inartful attempt to

provide the court, in so many words, with a general overview to a complex set of circumstances involving numerous defendants. Nevertheless, the complaint also contains numerous factual allegations of separate patterns of racketeering activity committed by various groups of defendants. Although agreeing that the global conspiracy, standing alone, would be insufficient, we are reluctant, at the relatively early Rule 12(b)(6) stage, to affirm the entire dismissal of Mylan's RICO and common law claims for failure to state a claim on the basis of the misleading additional language concerning joint activity. Accordingly, we reverse the decision to dismiss Counts 1, 2, and 4. We caution, however, that a claim held not dismissible at the Rule 12(b)(6) level must eventually still be proven.

I. STANDARD OF REVIEW

We review a district court's dismissal under Rule 12(b)(6) de novo. See, e.g., Schatz v. Rosenberg, 943 F.2d 485, 489 (4th Cir. 1991), cert. denied, ___ U.S. ___, 112 S. Ct. 1475 (1992). In general, a motion to dismiss for failure to state a claim should not be granted unless it appears certain that the plaintiff can prove no set of facts which would support its claim and would entitle it to relief. In considering a motion to dismiss, the court should accept as true all well-pleaded allegations and should view the complaint in a light most favorable to the plaintiff. See, e.g., De Sole v. United States, 947 F.2d 1169, 1171 (4th Cir. 1991).[4]

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[4] In light of the standard of review, we traditionally have viewed even poorly drafted complaints in a light most favorable to the plaintiff:

> [The] complaint, to say the

II. RICO CLAIMS (COUNTS 1 AND 2) AND STATE-LAW CLAIMS OF UNFAIR COMPETITION AND TORTIOUS INTERFERENCE WITH BUSINESS RELATIONS (COUNT 4)

The primary problem identified by Judge Smalkin with Mylan's two RICO

> least, was inartfully drafted . . . . In our view, however, a rule 12(b)(6) motion should be granted only in very limited circumstances. The Supreme Court has explained that "[t]he Federal Rules reject the approach that pleading is a game of skill in which one misstep by counsel may be decisive to the outcome and accept the principle that the purpose of pleading is to facilitate a proper decision on the merits." . . . We have long held "that a motion to dismiss for failure to state a claim for relief should not be granted unless it appears to a certainty that the plaintiff would be entitled to no relief under any state of facts which could be proved in support of his claim."

Rogers v. Jefferson-Pilot Life Ins. Co., 883 F.2d 324, 325 (4th Cir. 1989) (citation omitted) (quoting Conley v. Gibson, 355 U.S. 41, 48 (1957), and Johnson v. Mueller, 415 F.2d 354, 355 (4th Cir. 1969)).

counts and its state-law claims essentially boils down to the following allegation appearing in the beginning of Count 1:

> The racketeering acts committed by each of the defendants identified below were related to one another and formed a pattern of racketeering activity in that they were in furtherance of the common goals of profiting illegally at Mylan's expense and were focused upon undermining the integrity of the FDA approval process in order to improperly obtain economic advantage.

Third Am. Compl. ¶ 114. That statement, or more accurately, that "theme," was either repeated or incorporated by reference into Counts 2 and 4. The district court and the defendants have convincingly demonstrated that not one of the extensive allegations described in Mylan's complaint supports any claim that all of the defendants acted together, in a single, global pattern of racketeering

activity, driven by the united goal of profiting illegally at Mylan's expense.

In his opinion dismissing substantial portions of Mylan's First Amended Complaint, Judge Ramsey specifically rejected Mylan's theory of a "global conspiracy" among the various defendants. Mylan, he concluded, had failed to present any sufficient allegations to support such a claim. Mylan, 770 F. Supp. at 1066-68, 1077. In fact, Judge Ramsey noted that Mylan's allegations showed that the generic drug industry was one of intense competition, of continuous battles to obtain the all-important first FDA approval of a generic drug and, thus, the first place on the market. In light of that ambitious environment, it was at least as likely, he concluded, that the defendants' actions were the independent product of self-interested competition.

Id. at 1068 (noting that Mylan alleged "nothing tending to exclude the possibility that the defendants acted independently").[5]

Judge Smalkin quite plainly agreed with Judge Ramsey's conclusion that Mylan had not adequately pleaded a global conspiracy. He concluded, moreover, that Mylan, in its Third Amended Complaint, had continued to assert the same unsupported claim:

> Although Mylan does not use the expression "global conspiracy" in its complaint, it clearly asserts that the racketeering acts of the defendants were related, and that they formed a pattern of racketeering activity. This is, in effect, an assertion that some form of global pattern of action existed, in which all of the defendants

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[5] Accordingly, Judge Ramsey dismissed the anti-trust counts (Counts 4-40) and Count 3, Mylan's claim under RICO, 18 U.S.C. § 1962(d), of the First Amended Complaint. Those counts had been predicated upon the theory of a global conspiracy among the defendants.

> participated, Mylan's protestations [in its supporting memoranda] to the contrary notwithstanding.

Mylan Lab., Inc. v. Pharmaceutical Basics, Inc., 808 F. Supp. 446, 450-51 (D. Md. 1992). Judge Smalkin determined that Counts 1, 2, and 4, if permitted to proceed on a theory of global action, "would work a manifest injustice" on the defendants, as they "would be required to defend against claims which have already been shown to have no factual basis." Id. at 452. Accordingly, he dismissed with prejudice all three counts.

However, several separate patterns of racketeering activity or, in the words of the Third Amended Complaint, "series of schemes" can be gleaned from the allegations of Counts 1, 2, and 4. In dismissing with prejudice the RICO counts and the state-law claims, Judge Smalkin overlooked the viability of the three

counts independent of any global action pleading. In short, although the complaint does not support a claim of a global pattern among all of the defendants, it nevertheless, when read in a light most favorable to the plaintiff, sets forth separate patterns of racketeering acts committed by various groups of defendants. What these separate patterns have in common, it appears from the complaint, is the similar objective of expediting the ANDA approval process for self gain.

It must be remembered that Judge Ramsey, when reviewing the First Amended Complaint, dismissed only one RICO count in its entirety. He did not dismiss either the state law claims or, as against some of the defendants, the two counts alleging violations of RICO, 18 U.S.C. §§ 1962(a) and (c). Although we can appreciate Judge Smalkin's position

that an extremely complex case with a great divide between pleading and proof has lived long enough, we find that Judge Ramsey's analysis at the Rule 12(b)(6) stage, dealing essentially with pleading, not proof, accorded best with the authorities.

As Judge Ramsey properly noted, to state a claim under RICO, Mylan was required to allege a "pattern of racketeering." The statute requires "at least two instances" of racketeering activity. 18 U.S.C. § 1961(5). "Racketeering activity" is defined in 18 U.S.C. § 1961(1) and includes, inter alia, bribery, mail and wire fraud, and obstruction of justice. Further, a "pattern" requires a showing of a relationship between the predicate acts and a threat of continuing activity. H.J. Inc. v. Northwestern Bell Tel. Co., 492 U.S. 229, 239 (1989).

Mylan had alleged in the First Amended Complaint and continues to do so in the third version thereof as predicate acts for the RICO counts bribery, mail and wire fraud, and obstruction of justice. Judge Ramsey first concluded, and we do not disagree, that for the purposes of Rule 12(b)(6) Mylan had sufficiently alleged the predicate acts of bribery and obstruction of justice.[6] Next, he quite clearly examined whether Mylan had sufficiently pleaded some "pattern" of racketeering activity. Mylan, 770 F. Supp. at 1076 ("A holding that Mylan has sufficiently alleged the predicate acts of bribery and obstruction of justice does not end the inquiry into the sufficiency of Mylan's RICO claims. The next question is whether the acts

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[6] He ruled, however, that Mylan's claims of mail and wire fraud were insufficient. See infra Part III.

alleged constitute a sufficient 'pattern' of racketeering activity."). Although Judge Ramsey would not "attribute every predicate act to every defendant,"[7] he did proceed to review, as Judge Smalkin did not, any allegations as to patterns of racketeering acts allegedly committed separately by defendants ATI, Par, Quad, PBI, Vitarine, Quantum, AHP, the corporations' respective employees, and the defendant FDA employees. Id. at 1077. He recognized that Mylan's allegations clearly show that "each defendant's actions were focused on undermining the integrity of the FDA

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[7] Indeed, as Judge Smalkin noted in his ruling, such attribution clearly would have been improper in light of Judge Ramsey's ruling that there had been insufficient allegations to support a global conspiracy theory. Judge Ramsey instead "attributed the acts of the various agents to their corporate manufacturer employers" for the purposes of examining Mylan's showing of a "pattern." Id. at 1077.

approval process in order to improperly obtain advantage for themselves." Id. at 1076. For the purposes of the motion to dismiss, Judge Ramsey concluded, and, again, we do not disagree, that with respect to some of the defendants, Mylan had alleged separate schemes constituting patterns of racketeering. See id. at 1077-78; see, e.g., Third Am. Compl. ¶¶ 114(A), 121 (describing various and continuous acts of bribery and obstruction of justice).

Finally, Judge Ramsey also concluded that Mylan had sufficiently alleged the elements of the state law torts of unfair competition and malicious interference with business relations. Once again, although the incorporation by reference into Count 4 of the theme of global action is in error, it is not fatal to Mylan's state law claims. We agree with Judge Ramsey's conclusions and sustain

Count 4 of Mylan's Third Amended Complaint.

We recognize, as did Judge Smalkin, the error of retaining the language of a "joint conspiracy" or "global pattern" of racketeering. Despite the faulty draftsmanship, however, Mylan has again essentially set forth in Counts 1, 2, and 4, a "series of schemes" or separate patterns of racketeering involving generally a corporate defendant, its employees, and FDA defendants. See, e.g., Mylan, 770 F. Supp. at 1066 (noting that the various allegations of acts taken by discrete groups of defendants were "sufficient to support the conclusion that there were various agreements between the manufacturer defendants and the FDA defendants, i.e., that the former were paying the latter in return for first approval of the ANDAs"). In light of those allegations, it simply

does not appear "beyond a doubt" that Mylan could "prove no set of facts in support of its claim" which would entitle it to relief. Accordingly we find sufficient for the purposes of Rule 12(b)(6), Counts 1, 2, and also Count 4 of the Third Amended Complaint.[8]

III. MAIL AND WIRE FRAUD CLAIMS AS PREDICATE ACTS FOR THE RICO COUNTS

In its First and Third Amended Complaints, Mylan has alleged as

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[8] Appellees AHP and Quantum correctly observe that Judge Ramsey did not sustain against them any RICO claims set forth in the First Amended Complaint. Count 3, of course, was premised on the global conspiracy theory and thus was dismissed against all of the defendants. As to Counts 1 and 2, however, Judge Ramsey found that Mylan had failed to show a pattern of racketeering by AHP and Quantum:

> Quantum's employee J. Chang is alleged to have made a single $300 payment to Brancato. No other predicate acts are alleged . . . . [T]his Court holds that the single payment alleged cannot as a matter of law constitute a RICO pattern

predicate acts for the RICO counts mail and wire fraud claims. On appeal Mylan raises again the question of the

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> no matter how many statutes it violated. Accordingly, Mylan's RICO claims against AHP, Quantum and J. Chang must be dismissed for lack of a pattern of racketeering activity.

Mylan, 770 F. Supp. at 1078.

In its Third Amended Complaint, however, Mylan has added to its allegations of bribery with respect to defendants AHP, Quantum, and J. Chang. See Third Am. Compl. ¶ 114(A)(11). The allegations include the single $300 cash payment and five meals between 1986 and 1988. The meals, according to the complaint, largely were concentrated over a period of six months at the end of 1987, through the beginning of 1988. In support of the sufficiency of its new allegations, Mylan points out that, with respect to defendants Akzo, PBI, and Matkari, Judge Ramsey found a sufficient "pattern" of racketeering activity based on similar allegations. The allegations found sufficient consisted of a single monetary payment to an FDA employee and several paid meals. Thus, Mylan concludes, the RICO counts should be sustained against AHP, Quantum, and J. Chang because the new allegations of bribery sufficiently show a "pattern" of racketeering activity that is consistent with Judge Ramsey's rulings.

sufficiency of those allegations for the purposes of Rule 12(b)(6). In its First Amended Complaint, Mylan set forth at least two theories of mail and wire fraud. First, Mylan primarily contended that the predicate acts of mail and wire fraud were committed when a defendant mailed to the FDA allegedly false ANDAs, and the FDA, relying on the false submissions, then approved the applications. Thus, it was alleged, not only had the FDA been defrauded out of its ANDA approvals, but Mylan, too, had been harmed, in the sense that it had

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In light of the additions to the allegations, and in keeping with the overall tenor of Judge Ramsey's rulings with respect to the rest of the defendants, we find that the new allegations of bribery are sufficient for now to demonstrate a "pattern of racketeering activity." Thus, the RICO counts of the Third Amended Complaint must, at the Rule 12(b)(6) level, be sustained as against defendants AHP, Quantum, and Jin-Shung Chang.

been defrauded out of its rightful ANDA approval and its proper share of the generic drug market.

Judge Ramsey dismissed that theory of mail and wire fraud on the grounds that it was legally insufficient. Specifically, he first concluded that ANDAs in the hands of the government and awaiting approval were not "property" within the meaning of the mail fraud statute: "[T]he FDA cannot have been defrauded of its ANDA approvals within the meaning of the federal mail and wire fraud statutes. Accordingly, to the extent that Mylan's allegations of mail and wire fraud rely on this theory they must be dismissed." Mylan, 770 F. Supp. at 1073. Second, Judge Ramsey also concluded that the person allegedly deceived by the misrepresentations must be the same party who was injured by the misrepresentations in order to allege

sufficiently the predicate acts of mail and wire fraud. Id. (stating that "to the extent that Mylan's claim of mail and wire fraud rests on the grounds that it was injured by the defendant's false submissions to the FDA, the claim must fail").

However, in the First Amended Complaint Mylan also alleged as further support for the predicate acts of mail and wire fraud that, in conjunction with improperly approving the corporate defendants' ANDAs, the FDA defendants also mailed deficiency letters to Mylan requesting unwarranted and unjustifiable data in order to delay approval of Mylan's ANDAs and also mailed to the corporate defendants confidential information submitted by Mylan in order further to facilitate the approval of their ANDAs. See First Am. Compl. ¶ 103(D) and (E). Judge Ramsey, however,

also dismissed those allegations. In short, he found the allegations of fraud to be overbroad and conclusory and struck the applicable portions of the complaint pursuant to Federal Rule of Civil Procedure 9(b), which requires that circumstances constituting fraud shall be stated with particularity.

Given the facts as alleged in the instant case, we affirm a ruling that precludes Mylan from relying on, as its sole basis for the predicate acts in its RICO counts, the theory that the FDA was defrauded out of its ANDA approvals within the meaning of the mail and wire fraud statutes. However, Mylan, in its Third Amended Complaint has altered its allegations of mail and wire fraud. Specifically, the Third Amended Complaint contains new allegations of the fraudulent use of the mails against Mylan by defendants AHP, Quantum, Vitarine, and

their employees. The changes were made, Mylan has contended, to comply with all of Judge Ramsey's rulings with respect to the mail and wire fraud claims and to clarify that it was both deceived and injured by the defendants' acts. Thus, Mylan asserts, the Third Amended Complaint no longer seeks to rely solely on the fraudulent submission of ANDAs to the FDA and states with more particularity the remaining allegations of mail and wire fraud. Because Judge Smalkin dismissed the RICO counts for their continued use of the global conspiracy language, he did not consider the sufficiency of the "new" predicate acts alleged in support of the RICO claims. In light of our decision in Part II to sustain the RICO counts, we decline to address the mail and wire fraud allegations and remit the issue to the district court and also grant to the

parties an opportunity to consider further and, perhaps, to flesh out the new allegations on remand.

IV. COUNT 3 -- LANHAM ACT CLAIM

Count 3 of Mylan's Third Amended Complaint introduces a new claim, namely that defendants AHP, Quantum, PBI, and Par each violated § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), by making false and misleading advertisements and representations about their generic drug products. Mylan maintains that its complaint properly alleges that each of the defendants' package inserts, brochures, and other advertisements violated § 43(a) of the Lanham Act because they falsely represented or implied (1) that the defendants' drugs had been properly approved by the FDA and

(2) that the defendants' drugs were "bioequivalent" to Mylan's drugs.[9]

In order to constitute a violation of § 43(a) of the Lanham Act, the contested statement or representation must be either false on its face or, although literally true, likely to mislead and to confuse consumers given the merchandising context. See, e.g., Castrol Inc. v. Pennzoil Co., 987 F.2d 939 (3d Cir. 1993); Sandoz Pharmaceuticals Corp. v.

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[9] Mylan also has contended on appeal that its complaint further states that the defendants' advertising was false and misleading because the defendants "omitted to state the obviously material fact that the FDA's approval for [the] defendants' generic drugs was obtained by fraud." Mylan's contention is unpersuasive, however, because there simply are no allegations of "material omissions" in the complaint. Accordingly, even if these "omissions" created a cause of action under the Lanham Act -- a matter hotly disputed by the appellees -- it has no bearing in the instant case in light of the failure to plead such a claim.

Richardson-Vicks, Inc., 902 F.2d 222 (3d Cir. 1990); see also Procter & Gamble Co. v. Chesebrough-Pond's Inc., 747 F.2d 114, 118 (2d Cir. 1984) ("'Section 43(a) of the Lanham Act encompasses more than blatant falsehoods.'" (quoting Vidal Sassoon, Inc. v. Bristol-Myers Co., 661 F.2d 272, 277 (2d Cir. 1981))). The parties dispute whether, for the purposes of Rule 12(b)(6), Mylan has sufficiently alleged the essential element of a false or misleading statement.

Judge Smalkin dismissed Mylan's Lanham Act claims on the grounds that the complaint failed to allege specifically that the defendants' drugs were not in fact bioequivalent. The failure to allege non-bioequivalence, he concluded, was fatal to Mylan's claim. Judge Smalkin correctly noted that, in order ultimately to succeed on its Lanham Act count, Mylan will have to show more

evidence than mere proof that the defendants' claims were supported by unpersuasive test results. "Rather the plaintiff must demonstrate that such tests are 'not sufficiently reliable to permit one to conclude with reasonable certainty that they established' the claim made." McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co., 938 F.2d 1544, 1549 (2d Cir. 1991) (emphasis added) (quoting Chesebrough-Pond's, 747 F.2d at 119). Given that ultimate standard and construing the complaint in a light most favorable to Mylan, we conclude that Count 3 alleges sufficient falsity to survive early dismissal under Rule 12(b)(6). The complaint repeatedly alleges, inter alia, that a defendant "falsely represented" that its product was "bioequivalent to its innovator counterpart and other approved generic equivalents;" that the product was

"entitled to an AB rating"[10] from the FDA; or that the product was the "generic alternative" to the innovator drug. See, e.g., Third Am. Compl. ¶¶ 140, 146, 151, 155. In support of those claims, Mylan has alleged that approval of the defendants' ANDAs had been obtained through "fraud" and ultimately was withdrawn and that the data for the ANDAs or bioequivalence studies had been "falsified" or was seriously "unreliable." In one instance Mylan even has alleged that bioequivalence studies either had not been performed or had been performed on a drug manufactured differently from the one advertised. See id. ¶ 138. In short, Mylan has set forth in the complaint sufficiently

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[10] According to the complaint, an "AB" rating indicates that the drug is considered to be "therapeutically equivalent" to the innovator drug. See, e.g., Third Am. Complt. ¶ 138.

particularized allegations of false or misleading representations to sustain, for now, Count 3. Put in other terms, we cannot say, when fairly reading the pleadings, that Mylan has failed to state a set of facts which, if proven, would entitle it to relief.[11]

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[11] In 1988, Congress amended § 43(a) of the Lanham Act. Trademark Law Revision Act of 1988, Pub. L. No. 100-667, tit. I, § 132, 102 Stat. 3946 (codified at 15 U.S.C. § 1125(a)). Our analysis of whether Mylan properly stated a claim for relief under § 43(a) is the same under both the former and the amended version of the section. Nothing in the amended § 43(a), which became effective in November 1989, alters the requirement that the plaintiff ultimately must prove that the contested statements or representations were false or misleading. In fact, according to the legislative history, the amendments largely codified the interpretation of § 43(a) that had been given by numerous courts. See S. Rep. No. 515, 100th Cong., 2d Sess. 40, reprinted in 1988 U.S.C.C.A.N. 5577, 5603.

In its opinion, the district court determined that the amended version of § 43(a) should apply to the claims against AHP and Quantum. Mylan has disagreed with that conclusion and has urged that the older version of § 43(a)

However, Mylan's claims that the defendants falsely represented that their drugs had been "properly approved by the FDA" must fail. First, in its complaint, Mylan nowhere points to any statement or representation in the defendants' advertising which declared "proper FDA approval." Moreover, that fatal deficiency cannot be cured by contentions that the very act of placing a drug on the market, with standard package inserts often used for FDA-approved drugs, somehow implies (falsely) that the drug had been "properly approved by the FDA." Such a theory is, quite simply, too great

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be applied to AHP and Quantum on remand. However, the applicability and scope of the amended version is not properly before us. The changes to § 43(a) raised the question of whether AHP's and Quantum's alleged statements had been made in "commercial advertising" within the meaning of the amended version. The district court resolved that issue in Mylan's favor, and the ruling has not been challenged by either party.

a stretch under the Lanham Act. We agree with the defendants that permitting Mylan to proceed on the theory that the defendants violated § 43(a) merely by placing their drugs on the market would, in effect, permit Mylan to use the Lanham Act as a vehicle by which to enforce the Food, Drug, and Cosmetic Act ("FDCA") and the regulations promulgated thereunder. An attempt, by ingenious pleading, to escape one principle of law by making it appear that another not truly appropriate rule is applicable appears to have been attempted.

Mylan, in short, is not empowered to enforce independently the FDCA. Cf. Sandoz, 902 F.2d at 230 ("The Lanham Act is primarily intended to protect commercial interests . . . . [It] provides a private remedy to a commercial plaintiff who meets the burden of proving that its commercial interests have been

harmed by a competitor's false advertising. The [FDCA], in contrast, is not focused on the truth or falsity of advertising claims" but on protecting the public interest in safety and efficacy (citations omitted)); see also FDCA, 21 U.S.C. § 337 (authorizing enforcement proceedings only by the United States and, under some circumstances, by a state). In order to state a proper claim for relief under § 43(a) of the Lanham Act, Mylan was required to point to some claim or representation that is reasonably clear from the face of the defendants' advertising or package inserts. That it did not do. Accordingly, that part of the complaint which alleges that the defendants violated the Lanham Act by representing or implying that the drugs had been "properly approved by the FDA" must be rejected.

V. DISMISSAL WITH PREJUDICE

In light of our rulings with respect to the four counts of Mylan's Third Amended Complaint, we need not address whether Judge Smalkin abused his discretion in dismissing with prejudice Mylan's complaint and in refusing to permit further amendments. We agree with Judge Smalkin, however, that the case has remained extremely long in the pleading stage, and we expect the case to proceed with no further motions to amend (other than one designed to comply with a suggestion herein). See, e.g., Foman v. Davis, 371 U.S. 178, 182 (1962) (Appropriate reasons to prohibit further amendments of a complaint include "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance

of the amendment, [and] futility of amendment.").

VI. DEFENDANTS RAJU VEGESNA AND JIN-SHUNG CHANG

Mylan also has requested that the indefinite suspension of litigation against defendant Raju Vegesna, a former ATI executive, be lifted and that the service of process on defendant Jin-Shung Chang, former executive at Quantum, be deemed effective. Appellees AHP and Quantum have taken no position on the two issues.

Defendant Vegesna has disappeared and is no longer represented by counsel. He apparently pleaded guilty to two counts of interstate travel in aid of racketeering based on the conduct alleged in the instant case, had been served, and had retained counsel. In May 1992, Judge Ramsey declined to lift the suspension of

proceedings but noted that the stay would be lifted and the case against Vegesna would proceed as soon as he was located.

Mylan has requested that the panel lift the indefinite suspension of proceedings so that it can continue to prosecute its claims against Vegesna. According to Mylan, Vegesna should suffer a default judgment as a result of his disappearance. Because we have reversed the dismissal with prejudice and because it has been roughly a year or more since the district court last ruled on the issue, the district court should be approached by Mylan and requested to reconsider the facts and the propriety of the suspension of proceedings as to defendant Vegesna.

Defendant Chang also was indicted for illegal conduct, but he, too, left the jurisdiction. According to Mylan, it repeatedly attempted to serve Chang at

his last known address and also at a closing of his New York residence. At the closing, Mylan attempted to serve the papers on Mrs. Chang, but Mrs. Chang refused to take them. Judge Ramsey did not accept Mylan's acts as proper service. At the time of Judge Ramsey's ruling, it was believed that Chang was in Taiwan. The question of Chang's current whereabouts, if known, and the propriety of service of process in light of any developing circumstances add up to questions of fact which should be taken up by the parties with the district court.

The judgment is

REVERSED.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

MYLAN LABORATORIES, INC.,	:	
Plaintiff	:	
		CIVIL ACTION
v.	:	NO. S 90-1096
PHARMACEUTICAL BASICS, INC., et al.,	:	
	:	
Defendants		
	:	

W. Stephen Cannon and Joseph H. Gibson, Wunder, Diefenderfer, Ryan, Cannon & Thielen, Washington, D.C., Michael C. Silverberg, Morvillo, Abramowitz, Grand, Iason & Silverberg, P.C., New York, New York, Andrew G. Fusco, Fusco & Newbraugh, Morgantown, West Virginia, Price O. Gielen, Neuberger, Quinn & Gielen, Baltimore, Maryland, for plaintiffs, Mylan Laboratories, Inc.

Donald J. Mulvihill, Cahill, Gordon & Reindel, Washington, D.C., for defendants Pharmaceutical Basics, Inc.

Richard M. Cooper, Richard S. Hoffman, and David Kiernan, Williams & Connolly, Washington, D.C., for defendants Par Pharmaceutical, Inc., and Quad Pharmaceuticals, Inc.

Ty Cobb and Janet McDavid, Hogan & Hartson, Washington, D.C., for defendants American Therapeutics, Inc.

John Sullivan, Lord, Day & Lord, Barrett Smith, New York, New York for defendants Vitarine Pharmaceuticals, Inc.

Peter Zimroth and Kenneth Handal, Arnold & Porter, New York, New York for defendants American Home Products Corp. and Quantum Pharmics, Ltd.

Hamilton P. Fox, III, Sutherland, Asbill & Brennan, Washington, D.C., for defendant Raj Matkari.

Andrew Krulwich and Walter Andrews, Wiley, Rein & Fielding, Washington, D.C., for defendant Ashok Patel.

Steve Salky, Zuckerman, Spaeder, Goldstein, Taylor & Kolker, Washington, D.C., for defendant Dilip Shah.

Michael P. Bell, Selzer & Roberge, Rockville, MD, for defendant Salvatore J. Pinella.

Filed: December [illegible], 1992

Smalkin, District Judge.

MEMORANDUM OPINION

This case is currently before the Court on multiple defense motions: defendant Pharmaceutical Basics, Inc.'s ("PBI") Motion to Dismiss Count Three of

Plaintiff's Third Amended Complaint for Failure to State a Claim or, in the alternative, for Partial Summary Judgment, and its Motion for Judgment on the Pleadings; defendants American Home Products Corporation's ("AHP") and Quantum Pharmics, Ltd.'s ("Quantum") Motion to Dismiss the Third Amended Complaint for Failure to State a Claim; defendants Par Pharmaceutical, Inc.'s ("Par") and Quad Pharmaceuticals, Inc.'s ("Quad") Motion for Judgment on the Pleadings, as well as their Motion to Join the Motions to Dismiss of PBI, AHP and Quantum; defendant Dilip Shah's Motion for Judgment on the Pleadings and to Join Motions of Other Defendants; defendant Salvatore J. Pinella's Motion to Dismiss the Third Amended Complaint and to Join Motions of Other Defendants; and defendant Raj Matkari's Motion for Judgment on the Pleadings, and Motion to

Join the Motions of AHP and Quantum to Dismiss the Third Amended Complaint, as well as his Motion to Join the Motions of Par and Quad for Judgment on the Pleadings. The plaintiff, Mylan Laboratories, Inc. ("Mylan") has responded, and many of the defendants have replied. No oral hearing is necessary. Local Rule 105.6 (D. Md.).

I. FACTUAL BACKGROUND

The facts of this case were set out in detail in an earlier opinion of the court. Mylan Laboratories, Inc. v. Akzo, N.V., 770 F. Supp. 1053, 1057-58 (D. Md. 1991) (Ramsey, J.). Briefly, the plaintiff, Mylan, is a corporation which is in the business of developing, manufacturing, selling and distributing prescription drugs. The defendants include corporations which develop, manufacture, sell and distribute generic drugs (defendants PBI, AHP, Quantum, Par,

Quad, Vitarine Pharmaceuticals, Inc. ("Vitarine") and American Therapeutics, Inc. ("ATI")), individuals who, at all relevant times, were employees or officers of these corporate defendants (defendants Raj Matkari, Ashok Patel, Dilip Shah, Raju Vegesna, Mohammed Azeem, Steven F. Colton and Jin-Shung Chang), and individuals who, at all relevant times, were employees of the Food and Drug Administration ("FDA") (Charles Chang, David Brancato, Walter Kletch, Jan Sturm and Salvatore Pinella).

Mylan alleges that the corporate defendants paid illegal gratuities to the FDA defendants, with the knowledge, direction, or participation of the corporate officers or employee defendants, in order to facilitate FDA approval of the corporate defendants' abbreviated new drug applications ("ANDA") for generic drugs. Mylan also

alleges that the same defendants impeded FDA approval of Mylan's ANDAs for the same drugs, and that non-public information, obtained from the ANDAs of Mylan and other drug manufacturers, was transmitted to the corporate defendants by the FDA defendants. Mylan further alleges that some corporate defendants made false representations that they had produced a generic equivalent of a particular drug (Maxzide) without infringing Mylan's patent; that corporate defendants submitted false data to the FDA in order to obtain approval for ANDAs to which they were not entitled; and, finally, that corporate defendants unfairly competed with Mylan by use of false and misleading commercial advertising.

Mylan's first complaint in this case was filed on June 8, 1989, in the United States District Court for the District of

Columbia. On March 27, 1990, Judge Hogan of that court determined that the case had been improperly filed in the District of Columbia and transferred the case to this Court.

Mylan filed a First Amended Complaint, consisting of 41 counts, with this Court on July 26, 1990. In an opinion dated August 15, 1991, Judge Ramsey dismissed Count 2 of Mylan's complaint as to defendants Matkari, Patel, Shah and Vegesna, as well as defendants AHP, Quantum and J. Chang. Judge Ramsey also dismissed Counts 3 through 40 of the complaint as against all defendants.

On March 9, 1992, Mylan moved to file a Second Amended Complaint. Judge Ramsey, however, denied the motion because of Mylan's failure to comply with Local Rule 103.6.c regarding the highlighting of amendments. Mylan

supplied a highlighted copy of its complaint on June 11, 1992, as well as a revised Motion to Amend. In the interim, the case had been transferred from Judge Ramsey to me. After requiring Mylan to conform its Complaint to Judge Ramsey's ruling dismissing a former defendant from the case, Mylan's Motion to Amend was granted. On July 23, 1992, Mylan filed its Third Amended Complaint, which is the subject of the current gaggle of defense motions.

In the Third Amended Complaint, Mylan has alleged four counts against nineteen defendants. Counts One and Two arise under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 et seq. Count One is asserted against all of the defendants. Count Two is asserted against defendants PBI, Quad, ATI, Vitarine, AHP, Quantum,

Azeem, J. Chang, C. Chang, Brancato, Kletch and Sturm.

Count Three arises under the Lanham Act, 15 U.S.C. § 1125, and is asserted against defendants AHP, Quantum, PBI and Par. Count Four arises under Maryland state law, with jurisdiction of this Court arising under 28 U.S.C. § 1332; it is a claim of unfair business competition and malicious interference with business relations, asserted against all of the defendants.

II. LEGAL STANDARDS GOVERNING MOTIONS TO DISMISS

A motion to dismiss for failure to state a claim, pursuant to Fed. R. Civ. P. 12(b)(6), should not be granted unless the plaintiff can prove no set of facts which support his claim and which entitle him to relief. Conley v. Gibson, 355 U.S. 41, 45-46 (1957). In making this determination, the Court

should construe the complaint, and the allegations contained therein, favorably to the pleader. Scheuer v. Rhodes, 416 U.S. 232, 236 (1974). The Court must not, however, consider conclusions of law or unwarranted deductions of fact. Mylan, 770 F. Supp. at 1059. Nor can the Court consider any facts, allegations or assertions made by the plaintiff which are contained in legal memoranda other than the complaint. It is well-founded that a complaint cannot be amended by the briefs in opposition to a motion to dismiss. Mylan, 770 F. Supp. at 1068.

III. THRESHOLD MATTERS

Defendants Matkari, Pinella, Par, and Quad have made various motions to join, pursuant to Fed. R. Civ. P. 12(g). These motions will be granted, by an order to be entered separately.

The Court also notes that there have been several changes made by Mylan when

preparing the Third Amended Complaint to conform with the removal of the former defendant Akzo N.V. from the case. See AHP's and Quantum's Motion to Dismiss, at 6, n.3.[1] These changes were brought to the Court's attention by the defendants in this case, and not by Mylan, which had a responsibility under Local Rule 103.6.c to highlight all changes made to the complaint. Indeed, Mylan simply acknowledges their existence, dismissing them as "minor errors." Mylan Response Memorandum, at 5, n.3.

Mylan's cavalier attitude to its failure to alert this Court to yet another violation of the local rule against non-highlighted changes to the

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[1] The Court recognizes, with appreciation, the efforts of the unnamed law clerk or paralegal who was presumably given the unenviable task of comparing the different versions of Mylan's complaint, and who was still alert enough to note these changes.

complaint, especially in the face of this Court's previous ruling, is astounding. Arduous though the task of checking every word of the complaint for additions may be, it was the task of Mylan, and not the defendants, to do so. Mylan's failure to draw the Court's attention to these changes, or to apologize for its actions, while not necessarily sufficient to merit a dismissal of this case for non-compliance with the Court's earlier ruling, or a sanctioning of those attorneys involved in the preparation of this deficient complaint, does no credit to any of those responsible for this present incarnation of Mylan's complaint.

IV. DISMISSAL OF THE COMPLAINT FOR VIOLATION OF COURT'S PRIOR ORDER

Defendants AHP, Quantum, and PBI have moved for dismissal of Mylan's complaint for a violation of this Court's

prior order. The defendants claim that Mylan's complaint is fundamentally, and fatally, flawed, that it has been from the inception of this litigation, and that Mylan, having been afforded multiple opportunities to produce a viable complaint, has failed to rectify these fundamental flaws; therefore, its complaint should now be dismissed with prejudice.

The substance of the defendants' claim revolves around Counts One, Two, and Four of Mylan's Third Amended Complaint. In Counts One and Two, Mylan asserts that the defendants acted in violation of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), Count One alleging a violation of 18 U.S.C. § 1962(c)[2] and Count Two alleging a

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[2] The language of this portion of the act is as follows:

It shall be unlawful for any

violation of § 1962(a).[3] In Count Four, Mylan reasserts these claims, in the guise of a Maryland common law claim of unfair competition and malicious interference with business relations, against all defendants.

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person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt.

[3] The pertinent language of this portion of the statute is as follows:

> It shall be unlawful for any person who has received any income derived, directly or indirectly, from a pattern of racketeering activity . . . to use or invest, directly or indirectly, any part of such income, or the proceeds of such income, in acquisition of any interest in, or the establishment or operation of, any enterprise which is engaged in, or the activities of which affect, interstate or foreign commerce.

In furtherance of its claim, Mylan asserts that "[t]he racketeering acts committed by each of the defendants . . . were related to one another and formed a pattern of racketeering activity in that they were in furtherance of the common goals of profiting illegally at Mylan's expense and were focused upon undermining the integrity of the FDA approval process in order to improperly obtain economic advantage." Mylan Complaint, at ¶ 114. The defendants claim that this language, which is contained within Count One and which is incorporated by reference into Counts Two and Four, asserts a "global conspiracy" among all of the defendants -- a theory that was explicitly rejected by Judge Ramsey in his previous opinion. Mylan, 770 F. Supp. at 1068.[4] Thus, claim the

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[4] A decision with which this Court is in entire agreement.

defendants, because Mylan is reasserting a previously rejected theory of liability, it is in violation of the Court's previous order, and this complaint should be dismissed in consequence. Furthermore since this Court has already instructed Mylan that no further amendments to the complaint will be allowed, the complaint should be dismissed with prejudice.

Mylan asserts that Judge Ramsey had a chance to analyze the language of these two counts when he ruled on the motions to dismiss the previous complaint. Mylan contends that Judge Ramsey found that the language of these two claims was "sufficient" and that, therefore, it resubmitted the same language, adding additional allegations against the defendants. Thus, it argues, the "law of the case doctrine" counsels against dismissing the complaint. In addition,

Mylan has asserted, in motion papers, that it does not intend for the language in these counts to be read as asserting a global conspiracy. Mylan, Response Memorandum, at 8.

A. Mylan's Intention that Complaint Not be Read to Assert a Global Conspiracy

Although Mylan does not use the expression "global conspiracy" in its complaint, it clearly asserts that the racketeering acts of the defendants were related, and that they formed a pattern of racketeering activity. This is, in effect, an assertion that some form of global pattern of action existed, in which all of the defendants participated, Mylan's protestations to the contrary notwithstanding. Indeed, Mylan's effort to "go the extra mile," Mylan, Response Memorandum at 8, is unavailing and, indeed, inappropriate since, as noted above, the language of the complaint

cannot be amended by the briefs and motion papers filed in opposition to a motion to dismiss.[5]

B. The Law of the Case Doctrine

Mylan's contention that this language comes to the Court's consideration, in effect, "pre-approved" by Judge Ramsey is not persuasive. It is true that Judge Ramsey did not dismiss these counts, even though they contained the "common pattern" language which is now at issue. Nor does the Court dispute that fact that Mylan is seeking now, as

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[5] Mylan asserts that its efforts in this regard were merely an attempt to "clarify any possible lingering doubt" as to the meaning of the language of the complaint. Mylan, Reply Memorandum, at 8, n.5. In its enthusiasm to clarify its meaning, however, Mylan speaks of its intent as to the meaning of the language in the complaint. Mylan's intent, of course, is irrelevant to the Court's analysis of what the language used by Mylan in the complaint actually means, and the Court is not, and cannot be, influenced in this analysis by a subsequently filed explanation of the meaning behind the language.

it did previously, to assert separate claims against each of the defendants. Mylan, Reply Memorandum, at 7-8. The flaw in Mylan's position is its apparent contention that, under the law of the case doctrine, the Court is now bound to accept the language of Counts One, Two, and Four simply because it was not expressly rejected earlier.

The law of the case doctrine is "an amorphous concept." Arizona v. California, 460 U.S. 605, 618 (1983). As the Supreme Court has defined it, the doctrine "posits that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case." Id. (citations omitted). There is, however, an exception to this rule, which provides for the court to depart from a prior ruling "if convinced that it is

clearly erroneous and would work a manifest injustice." Id., n.8.

The question of whether rulings by one district judge are binding on a subsequent district judge, under the law of the case doctrine, is "not a matter of rigid legal rule, but more a matter of proper judicial administration which can vary with the circumstances. It may sometimes be proper for a district judge to treat earlier rulings as binding, sometimes not." Hill v. BASF Wyandotte Corp., 696 F.2d 287, 290 n.3 (4th Cir. 1982) (citations omitted). Indeed, some courts have held that the law of the case doctrine is "no more than a principle of comity; as such, it should give way, if the needs arise, to the interests of justice and economy when those interests would be flouted by rigid adherence to the rule." Gallimore v. Missouri Pac. Ry., 635 F.2d 1165, 1172 (5th Cir. 1981).

The application of the doctrine is one "within the sound discretion of a trial judge conducting his court in the interest of furthering the administration of justice." Id., quoting United States v. Koenig, 290 F.2d 166, 172 (5th Cir. 1961), aff'd sub nom. DiBella v. United States, 369 U.S. 121 (1962).

Inherent within the law of the case doctrine is the requirement that there have been a ruling on a point of law. In the case before this Court, however, all that Mylan can point to is the failure of Judge Ramsey to dismiss two of the counts at issue here. Judge Ramsey engaged in no discussion of the language at issue, other than to note that, in considering whether Mylan had alleged a pattern of racketeering activity against the defendants, he would not attribute every predicate act to every defendant, "despite Mylan's urging." Mylan, 770

F. Supp. at 1077.[6] In this Court's judgment, therefore, the fact that Judge Ramsey did not dismiss these counts based on his holding that no global conspiracy existed does not constitute a ruling on the issue of whether Mylan has, in fact, alleged a pattern of racketeering activity against all defendants. All that can be read into Judge Ramsey's previous opinion is that the issue was, and therefore is, unresolved.

Thus, this Court holds that the law of the case doctrine is inapplicable to the issue in question, and that Mylan has alleged a pattern of racketeering activity against all of the defendants in this case. Moreover, were this Court to

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[6] Judge Ramsey did observe that in Mylan's First Amended Complaint, there was a § 1962(d) claim which alleged a global conspiracy and, therefore, was dismissed, based upon his previous finding that no such global conspiracy existed. Mylan, 770 F. Supp. at 1068.

have held that Judge Ramsey had ruled on the issue, and that therefore the law of the case doctrine was applicable, it would nonetheless hold that Mylan had now made an allegation of a blanket pattern of activity, in violation of Judge Ramsey's previous ruling that there was, in fact, no global conspiracy. It is clear from the language of Mylan's Third Amended Complaint that such an allegation has been made, and thus, had Judge Ramsey found otherwise, this ruling would have been clearly erroneous, in that it would have been inconsistent with Judge Ramsey's holding on the global conspiracy issue. If allowed to stand, such a ruling would work a manifest injustice, in that the defendants would be required to defend against claims which have already been shown to have no factual basis.

C. Dismissal of the Third Amended Complaint

The defendants ask that Mylan's entire complaint be dismissed, with prejudice, for its violation of th Court's prior order. Certainly such a result, given the Court's conclusion that Mylan has asserted Counts One, Two, and Four of the complaint based on a theory which has previously been rejected by the Court, would be within the sound discretion of the Court. Such a result, however, would be overly harsh and would, perhaps, unduly penalize the client for its attorneys' failure to fully comprehend the meaning of the language in which they chose to frame Counts One, Two, and Four, as well as the significance of Judge Ramsey's prior ruling in this case. On the other hand, the Court cannot, and will not, permit yet another amendment, simply in order to

allow Mylan one more opportunity to rectify its flawed complaint. So to do would be, in essence, to write the complaint for the plaintiff.

This litigation has languished in procedural limbo for years. As previously noted by this Court in this case, the purpose of federal civil practice is to "secure the just, speedy, and inexpensive determination of every action." Fed. R. Civ. P. 1. For that reason, the parties in this litigation were put on notice that no further motions to amend pleadings would be entertained by this Court. Nothing in Counts One, Two, and Four of Mylan's Third Amended Complaint gives this Court any reason to reconsider this position now. Construing the complaint in the light most favorable to Mylan, this Court finds that Mylan can prove no set of facts which support its claim and entitle

it to relief as to Counts One, Two and Four.

For these reasons, an Order will be entered separately dismissing Counts One, Two, and Four of the Third Amended Complaint, with prejudice, as barred by prior order of Court.

V. LANHAM ACT

Count three of Mylan's Third Amended Complaint alleges a violation of the Lanham Act, 15 U.S.C. §§ 1117[7] and 1125(a), against defendants AHP, Quantum,

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[7] The pertinent language of this section is as follows:

> When a violation of any right of the registrant of a mark registered in the Patent and Trademark Office shall have been established in any civil action arising under this chapter, the plaintiff shall be entitled . . . to recover (1) defendant's profits, (2) any damages sustained by the plaintiff, and (3) the costs of the action.

PBI, and Par. Mylan alleges that these defendants falsely advertised and promoted certain of their drug products, thus injuring Mylan. In addition, Mylan claims that the conduct of the defendants was so egregious, because of the alleged fraud perpetrated on Mylan, the FDA, and the general public, as well as the endangerment of the health of those who received the defendants' products as a result of these claims, that the Court should, in the exercise of its discretion, award Mylan treble damages and attorney's fees.

The defendants contend that the Lanham Act counts in Mylan's complaint are time-barred under Maryland's statute of limitations for libel. Furthermore, they contend that, even if the count survives the limitations bar, it should be dismissed because the package inserts which form the basis of this claim are

not "advertising," as referred to in the Lanham Act, and also because the language contained within these inserts is not "false and misleading" within the meaning of the Act.

A. Statute of Limitations

The Lanham Act contains within it no specific statute of limitations. In this situation, "the settled practice has been to adopt a local time limitation as federal law if it is not inconsistent with federal law or policy to do so." Wilson v. Garcia, 471 U.S. 261, 267 (1985). The state statute should be "'the most appropriate' or 'the most analogous' state statute of limitations to apply to [the federal statutory law]." Id. (citations omitted). There is no authority as to the appropriate Maryland statute of limitations in Lanham Act cases, making this a case of first impression for this Court.

The defendants argue that the most appropriate and most analogous Maryland statute of limitations to apply to the Lanham Act is that for libel. According to the defendants, both libel and the Lanham Act provide a remedy to one who has been injured by false statements. Thus, they contend, the "most obvious" choice is for this Court to apply the one year Maryland statute of limitations for libel, Md. Cts. & Jud. Proc. Code Ann. § 5-105 (1989), rather than the general three year limitations period for other torts, id. at § 5-101. As support for this position, the defendants cite the Court to Bedi Photographics Corp. v. Polaroid Corp., No. 76-1107, unpublished op. (E.D. Pa. Aug. 11, 1980).

This is an ingenious argument, and one which, claim the defendants, would, if applied, bar Mylan from asserting its Lanham Act claims, since these were added

in July of 1992, thus after one year from the date of the alleged violations. Unfortunately for the defendants, the underlying premise of their argument, that libel and the Lanham Act are closely analogous, is invalid.

Libel is "[a] method of defamation expressed by print, writing, pictures, or signs." Black's Law Dictionary 824 (5th ed. 1979). Defamation is the "[h]olding up of a person to ridicule, scorn or contempt in a respectable and considerable part of the community; . . ." Id. at 375. Thus it is the act of traducing the individual which is at the heart of libel.

The Lanham Act, on the other hand, is concerned with the act of using a false statement of some kind in commerce. Although the Act does provide for a civil cause of action to one who does business and is likely to be damaged by the false

statement, there is no requirement that the false statement be about anyone, or any organization. Indeed, the false statement can refer to a false designation or origin, and thus not be about anyone at all. Implicit within the Lanham Act, however, is the notion that the false statement will induce a customer to buy from the person or business making the false statement, rather than from someone else. The damage suffered by a plaintiff in a Lanham Act lawsuit will, therefore, be loss of business. This situation is more closely analogous to fraud, which is "[a]n intentional perversion of truth for the purpose of inducing another in reliance upon it to part with some valuable thing belonging to him or to part with a legal right." Black's Dictionary at 595.

It is true, as noted by the court in Construction Technology v. Lockformer Co., Inc., 704 F. Supp. 1212 (S.D.N.Y. 1989), that the Lanham Act is silent on the issue of scienter, which is so much a part of fraud. It is, however, impossible to find a perfect fit when looking for state legislation which is most closely analogous to federal statutes, nor is perfection the test. Although scienter is not a necessary element of a Lanham Act claim, this Court cannot agree with the court in Lockformer that intent to mislead the public is "largely irrelevant in determining if consumers likely will be confused as to source." Lockformer, 704 F. Supp. at 1220. Clearly the degree to which a business intends to mislead the public will bear on how carefully it undertakes the deception and, therefore, the likelihood of its success.

This Court also notes that a central consideration for the New York court was New York State's six year statute of limitations in fraud cases, as opposed to the one year statute of limitations for libel, and the three year statute of limitations for injury to property. That court determined that the more appropriate statute of limitations was that pertinent to property injury, in the process rejecting the analogy to libel for much the same reason as that stated by this Court. In Maryland, however, there is no separate statute of limitations for fraud. Thus, even were the New York court's rationale to be adopted here, the result would be a three year statute of limitations. It is perhaps for this reason that the defendants chose to cite Bedi, an unpublished opinion which has been criticized even in Pennsylvania for its

unconvincing analysis, see Monkelis v. Scientific Systems Services, 653 F. Supp. 680, 684 (W.D. Pa. 1987), rather than Lockformer, which raises a valid question about the closeness of the fraud analogy.

For the stated reasons, this Court finds that the most appropriate, and most analogous, Maryland statute of limitations is the three year general statute of limitations provided for in § 5-101 of the Annotated Code of Maryland.[8]

1. Relation Back

The defendants next argue that Mylan's claim against them under the

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[8] In reaching this decision, the Court joins a long line of other federal courts who also have held that the Lanham Act and fraud are analogous for limitations purposes: Johannsen v. Brown, 797 F. Supp. 835, 840 (D. Or. 1992); Unlimited Screw Products, Inc. v. Malim, 781 F. Supp. 1121, 1126 (E.D. Va. 1991); Monkelis, 653 F. Supp. at 684 (W.D. Pa. 1987); PepsiCo, Inc. v. Dunlop Tire and Rubber Corp., 578 F. Supp. 196, 199 (S.D.N.Y. 1984); Fox Chemical Co. v. Amsoil, 445 F. Supp. 1355, 1357 (D. Minn. 1978).

Lanham Act cannot be related back under Fed. R. Civ. P. 15(c).[9] They contend that the Lanham Act claim does not arise out of the same conduct, transaction, or occurrence which was set forth in the original (1989) complaint. AHP and Quantum note that they were not even named in the original complaint, which addressed alleged illegal activity by some, but not all, of the defendants listed in the current complaint. In particular, they note that the issue of Quantum's advertising, and the allegations of consumer confusion, was not part of the original complaint.

The defendants do, however, acknowledge that Mylan's Lanham Act claim is related to its previous claim of fraud

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[9] The Court notes that the language of Rule 15(c) was amended, effective December 1, 1991. The pertinent language for the Court's purposes here, however, was unchanged.

on the FDA. In fact, they disparage the substance of the claim as merely an attempt to "bootstrap" this claim into one cognizable under the Lanham Act. Whether or not this is true, it is indisputable that, to the extent that this claim relates to the fraud on the FDA claim, the defendants recognize it as arising from the same conduct, transaction, or occurrence as that claim. That is all that is required to invoke relation back under Fed. R. Civ. P. 15(c). It is of no consequence that the claim is brought under a different statute. "The fact that an amendment changes the legal theory on which the action initially was brought is of no consequence if the factual situation upon which the action depends remains the same and has been brought to defendant's attention by the initial pleading." 6A C. Wright, A. Miller & M. Kane, Federal

Practice and Civil Procedure 2d § 1497 at 94-95 (1990). Thus it is clear that, as to PBI and Par, the two defendants named in Count Three who were also defendants in the original complaint, the Lanham Act claims relate back.

The more complex question is whether the allegations against AHP and Quantum, the two defendants who were added after the filing of the first complaint, should relate back to the filing of the first complaint. The first complaint in this case was filed on June 8, 1989. AHP and Quantum were added to the complaint by order of Judge Ramsey dated July 26, 1990. The Fourth Circuit has observed that three elements must be satisfied in order for relation back under Rule 15(c) to be accomplished. These elements are: "(1) same transaction or occurrence; (2) the new party had notice of the action prior to the expiration of the statute of

limitations; and (3) he knew or should have known that but for a mistake in identity the action would have been brought against him." Weisgal v. Smith, 774 F.2d 1277, 1279 (4th Cir. 1985).

The first of these elements, the same transaction or occurrence, has, as demonstrated above, been met here. The second element requires more analysis. As noted above, AHP and Quantum were added to the complaint on July 26, 1990. Mylan alleges, against these two defendants, a pattern of misleading advertising which began in December of 1985 and continued until May of 1989.

In order to calculate the expiration of the statute of limitations, it is necessary to determine the time of accrual of the action. Even in a case such as this, where a state statute of limitations is used, it is federal law that determines the accrual of a cause of

action. Hooper v. Sachs, 618 F. Supp. 963, 979 (D. Md. 1985), aff'd, 823 F.2d 547 (4th Cir. 1987). "Under the federal rule, the time of accrual is that point in time when the plaintiff knows or has reason to know of the injury which is the basis of the action." Id. (citations omitted).

In the present case, Mylan alleges that AHP and Quantum made false statements in commercial advertising concerning four separate drugs, a generic version of Maxzide, as well as Temazepam, Lorazepam and Fenoprofen, at different times. The range of dates for the alleged false advertising of the generic equivalent of Maxzide (Mylan's name for a product which is composed of a combination of triamterene and hydrochlorothiazide) is August, 1988 until May, 1989; for Temazepam, July, 1986 until September, 1987; for

Lorazepam, December, 1985 until November, 1987; and for Fenoprofen, November, 1988 until May, 1989. However, it cannot be said with any certainty that Mylan knew of the injury which is the basis of the action at that time. Although Mylan must be held to have had knowledge of these advertisements, they cannot be charged with knowledge of the alleged false statements contained within these advertisements until some time after the FDA conducted inspections of Quantum's facilities, during the period of August, 1989 until October, 1989. The FDA published notice that it had become aware of the submission of false data by Quantum as to triamterene and hydrochlorothiazide tablets in June, 1990. Third Amended Complaint at ¶ 100. In November of 1990, the FDA announced that Quantum had agreed to withdraw the ANDAs for forty additional drugs,

including lorazepam tablets. Thus, the earliest date at which Mylan could be said to have known about the allegedly false statements of AHP and Quantum (and therefore the date of the accrual of its cause of action under the Lanham Act) was June of 1990.[10]

For the purposes of the second prong of the Weisgal test, therefore, the new parties to the action, AHP and Quantum, had notice of the action in June, 1990, the month in which Mylan added the defendants to the complaint. Thus they clearly had notice of the action prior to

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[10] Mylan provides no information concerning its discovery that AHP and Quantum had allegedly made false statements concerning Fenoprofen. However, the FDA appears to have begun its revelations of the submission of false data with the June 1990 publication in the Federal Register, and this Court will accept that date for the purposes of calculating the time of accrual of Mylan's cause of action.

the expiration of the three year Maryland statute of limitations.[11]

It is upon the third prong of the Weisgal test which Mylan flounders. It must show that AHP and Quantum knew or should have known that, but for a mistake in identity, the action would have been brought against them. No such showing has been made, or even attempted, by Mylan. Nor do the circumstances of this case indicate that such a showing could be made. Thus this Court finds that there is no relation back of the Lanham

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[11] This analysis is not altered by the fact that the Lanham Act claims against all defendants were added to the complaint only in July of 1992. For the purposes of this prong of the Weisgal test, it is sufficient for Mylan merely to show that the defendants were aware of the action prior to the expiration of the relevant statute of limitations. Thus, even were it held that AHP and Quantum were only aware of the Lanham Act claims in July of 1992, the notice would still fall within the three year statute of limitations.

Act claims against AHP and Quantum to the filing of the original complaint.

This having been said, however, the relation back argument is somewhat academic. Although the Lanham Act claims against AHP and Quantum fail the Weisgal test, and therefore do not relate back to the filing of the original complaint, they do arise out of the same conduct, transaction or occurrence alleged against the defendants in the First Amended Complaint, which was filed in June, 1990. Therefore, under the above analysis performed for PBI and Par, the Lanham Act claims relate back to the filing of that complaint, since it was the "original pleading" for these defendants, within the contemplation of Fed. R. Civ. P. 15(c).

Therefore, this Court finds that Mylan's Lanham Act claims against PBI, AHP, Par and Quantum are properly before

this Court, and are not time-barred under the appropriate statute of limitations.

B. November Amendment of the Lanham Act

In November 1988, Congress amended the language of 15 U.S.C. § 1125 "sharpening the section's focus on false and deceptive advertising." Alpo Petfoods, Inc. v. Ralston Purina Co., 913 F.2d 958, 963 n.6 (D.C. Cir. 1990).[12]

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[12] The pre-amendment language of § 1125(a) is as follows:

> Any person who shall affix, apply, or annex, or use in connection with any goods or services, or any container or containers for goods, a false designation of origin, or any false description or representation, including words or other symbols tending falsely to describe or represent the same, and shall cause such goods or services to enter into commerce, and any person who shall with knowledge of the falsity of such designation of origin or description or representation cause or procure the same to be transported or used in commerce or deliver the same to any

This amendment became effective in November, 1989. 15 U.S.C. § 1051, note. Mylan has assumed that, since the

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> carrier to be transported or used, shall be liable to a civil action by any person doing business in the locality falsely indicated as that of origin or in the region in which said locality is situated, or by any person who believes that he is or is likely to be damaged by the use of any such false description or representation. 15 U.S.C. § 1125 (1982).

By contrast, the language of the 1988 amendment is as follows:

> Any person who, on or in connection with any goods or services, or container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false, or misleading description of fact, or false or misleading misrepresentation of fact, which--
>
> (1) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the

original complaint in this case was filed on June 8, 1989, the pre-1988 language will apply. Mylan, Response Memorandum, at 42, n.24. As with all else in this case, however, the situation is neither as simple nor as straightforward as the parties assume or the Court might wish.

The issue of the retroactivity of legislative enactments is complex and, at present, in flux. Until recently, courts had applied the law which was in effect

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> origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or
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> (2) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,
>
> shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such an act. 15 U.S.C. § 1125 (1982 & Supp. 1992).

at the time they rendered their decisions. Bradley v. School Bd., 416 U.S. 696 (1974). The Supreme Court appeared to reverse its position on retroactivity in 1988, holding that: "[r]etroactivity is not favored in the law. Thus, congressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result." Bowen v. Georgetown University Hospital, 488 U.S. 204, 208 (1988). The Supreme Court has chosen not to enlighten the lower courts on the appropriate resolution of what Justice Scalia has described as an "irreconcilable contradiction." Kaiser Aluminum & Chemical Corp. v. Bonjorno, 494 U.S. 827, 841 (1990) (Scalia, J., concurring). Thus, the lower courts are reduced to divining the current state of the law by looking at such entrails as the current

composition of the Court (see Percell v. International Business Machines, Inc., 785 F. Supp. 1229, 1234 n.5 (E.D.N.C. 1992)), and the faint harmony between the lines of cases that some have been able to discern, when they are viewed in the context of "fundamental fairness." See Jaekel v. Equifax Marketing Decision Systems, Inc., 797 F. Supp. 486, 491 (E.D. Va. 1992).

This Court shares the frustration of other inferior courts forced to choose between two seemingly contradictory Supreme Court lines of authority. The Court also shares in the decision of the majority of these courts that it is the Georgetown Hospital rule which most closely represents the current position of the Supreme Court. Thus, in the absence of a specific Congressional indication to the contrary, the appropriate language for the Court to

consider is the language of the statute which was in effect at the time of the filing of the complaint. Since the Lanham Act contains no such Congressional indication, this Court concludes that it is the pre-1988 version of the Lanham Act which controls here, as to the defendants named in the original complaint.

As noted above, however, AHP and Quantum were not named in the original complaint. They were added to the First Amended Complaint when it was filed in this Court on July 26, 1990, well after the date on which the Lanham Act amendment took effect. For these parties, the Court will apply the post-1988 language of the statute, for the reasons stated above.

C. Substantive Disputes Concerning the Lanham Act Claims

Mylan has alleged that four of the defendants, American Home, Quantum, PBI

and Par, made use of false and misleading advertisements in promoting their various drug products, thus harming Mylan, in violation of the Lanham Act, 15 U.S.C. §§ 1117 and 1125(a) (1982 & Supp. 1992). The advertisements were placed in commercial publications, as well as appended to the drug products themselves in the form of "package inserts" and distributed to wholesalers, physicians and pharmacists.

1. Package Inserts

The defendants challenge Mylan's use of the package inserts to substantiate its Lanham Act claims. The defendants contend that package inserts cannot be considered advertising, because they are contained within the packaging of the product and thus cannot be seen or considered by the consumer until after the product has been purchased. Therefore, argue the defendants, there

can be no inducement to purchase attributed to the content of the package inserts, and thus they cannot constitute false or misleading advertising.

Mylan responds that the pre-1988 amendment language should control here, and therefore no requirement of "commercial advertising" exists. Rather, the statutory language is concerned only with a misrepresentation which is affixed, applied, annexed, or used in connection with any container for goods. Under this language, argues Mylan, the package inserts are actionable. Furthermore, Mylan contends that, even if the post-amendment language were to apply, the inserts should still be deemed to fall within the Lanham Act. It argues that "it is reasonable to infer" that had the inserts disclosed the fact that bioequivalence was uncertain and that the ANDAs were false, the drugs would have

been returned and no further purchases would have been made. Mylan, Response Memorandum, at 46.

As to AHP and Quantum, the Court will, as noted above, analyze Mylan's claims using the post-1988 amendment. The statute requires that any misrepresentation of the nature, characteristics, qualities or geographic origin of the goods must be made "in commercial advertising or promotion." 15 U.S.C. § 1125(a)(2).

An insert, contained within packaging, and which the consumer cannot see until <u>after</u> the purchase has been made, cannot, of course, be called commercial advertising. It is axiomatic that the purpose of commercial advertising is to <u>induce</u> the customer to purchase a product. Once the product has been purchased, the need to advertise has ceased. However, Mylan alleges that the

package inserts were also contained in the packaging of bottles which were provided as "samples." Mylan, Complaint at ¶ 138. To the extent that the inserts were provided in sample bottles, which are themselves a form of advertising, they must be considered as within the realm of "commercial advertising" as contemplated by the statute. The Court, therefore, cannot say that Mylan can prove no set of facts against AHP and Quantum which support its claim that the package inserts violate the Lanham Act, and will not grant the defendants' Motions to Dismiss based on the package inserts.

The Court will analyze Mylan's claims against PBI and Par under the pre-1988 amendment language of the Lanham Act. Here, the issue is somewhat less complex. The statute requires that the misrepresentations be affixed, applied or

annexed or used in connection with any container for goods, with no requirement that commercial advertising be an element. There is no question that the package inserts were affixed to the containers containing the drugs. Therefore, Mylan has alleged sufficient facts to defeat a motion to dismiss, and the defendants' Motions to Dismiss will be denied on this issue.

2. Brochures and Advertising Intended for Wholesalers, Physicians and Pharmacists

The defendants contend that the Lanham Act should not apply to any material sent by them to wholesalers, physicians and pharmacists. The rationale for this position is that the Lanham Act is intended to protect consumers from the effects of misrepresentation on the part of the manufacturer. Under the defendants' theory, however, neither wholesalers,

physicians nor pharmacists can be considered as "consumers." Rather, they are intermediaries, through which the products flow in the stream of commerce from the manufacturer to the ultimate consumer, who is the patient who purchases the drug.

Mylan counters that neither the pre- nor the post-amendment language of the Act requires that the ultimate consumer be the target of the advertising. It chooses to analyze the situation in terms of the "critical" consumer who is, in this case, either the wholesaler, physician or pharmacist. Mylan's position is that it is these people who make the ultimate determination as to which drug the consumer will take. The ultimate consumer rarely will choose between competing generic drugs, and will simply buy the drug which is dispensed by the pharmacist. Thus, according to

Mylan, it is the intermediary who is critical to the purchase of generic drugs, and not the consumer. Therefore the protections of the Lanham Act should extend to these "critical consumers." Mylan, Response Memorandum, at 47-48.

The statute itself does not refer to those to whom it is intended to protect, nor whether "ultimate" or "critical" consumers are necessary for its invocation. Case law indicates that the clear purpose of Congress was to protect the consumer. Vidal Sassoon, Inc. v. Bristol-Myers Co., 661 F.2d 272, 277 (2d Cir. 1981). That, however, does not significantly advance the analysis. Clearly, the advertising at issue in this case was directed at non-consumers, and yet the impact of this advertising on the consumer was potentially significant.

In a case relied upon by the defendants, Hertz Corp. v. Avis, Inc.,

725 F. Supp. 170 (S.D.N.Y. 1989), vacated, 732 F. Supp. 26 (1990),[13] the court held that "[a]dvertising that is not misconceived, misunderstood, or that fails to reach the consuming public does not come within the purview of the Lanham Act, which is aimed primarily at consumer protection." Id. at 171 (citations omitted). The court cites to two cases in order to support its position, neither of which, however, appears to stand for this proposition.

In National Association of Pharmaceutical Manufacturers, Inc. v. Ayerst Laboratories, Divisions of/and

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[13] This case was vacated after the parties agreed to a settlement. Therefore, as Mylan points out, it has no direct precedential value. Nor, indeed, would it have any direct precedential effect on this Court even were the opinion to have remained in effect, coming, as it does, from a federal district court in another district. The case is still relevant, however, for its analysis, and the Court will view it in that light.

American Home Products Corp., 850 F.2d 904 (2d Cir. 1988), the court held that "[t]he truth or falsity of the advertisement usually should be tested by the reactions of the public." Id. at 917, citing American Home Products v. Johnson & Johnson, 577 F.2d 160, 165 (2d Cir. 1978). This case involved a letter which was sent to pharmacists, and so the court's quotation of this dictum from an earlier Second Circuit opinion could, if interpreted generously, imply that the advertisements to pharmacists should be viewed within the context of public opinion. Any support that this might lend to the Hertz court's position, however, is undermined by reference to the Johnson & Johnson opinion. Here the court analyzed an advertising campaign which was directed at the general public. When read in this context, the court's opinion that the reactions of the public

should determine the effect of the advertising makes perfect sense. It is equally clear, however, that it has no relevance whatsoever when determining the effect of advertising which was specifically not targeted at the general public. In particular, Johnson & Johnson cannot support the proposition that advertising which does not reach the general public is not actionable under the Lanham Act.

In fact, this is a red-herring issue. Nothing in the language of the statute requires that the ultimate consumer, whoever that might be, suffer the ill effects, if any, of the misleading advertising. The case law, as analyzed above, gives only a false hope to the defendants here. The correct result must be that, under either the pre or post-amendment language of § 1125, the allegation that the advertising language

was false or misleading is sufficient to withstand a motion to dismiss, regardless of to whom the advertising was targeted. For this reason, the defendant's motion to dismiss will be denied as to this issue.

3. The Substantive Content of the Advertising Language

The final issue raised by the defendants is that Mylan has failed to allege that the statements made in the package inserts and in the commercial advertisements placed by the defendants were, in fact, false or misleading. Thus, claim the defendants, Mylan has failed to allege a set of facts which support its claim and which entitle it to relief.

Mylan responds that the language, and indeed the presence,[14] of the package inserts implied that the drugs had met

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[14] The package inserts were "in the standard format for FDA-approved drugs." Mylan, Response Memorandum, at 44.

with FDA approval, including the fact that true ANDAs had been submitted. Mylan also claims that it is reasonable to infer that the defendants' generic drugs are not bioequivalent to Mylan's innovator drug. Mylan also notes that, given discovery, it might be able to make the allegation that the drugs were not bioequivalent. Finally, Mylan contends that the language of the commercial advertising strongly implies that the AHP and Quantum ANDAs were true and not fraudulent.

The case law indicates that, in order to prevail on a Lanham Act claim, a plaintiff must show that a contested statement is in fact false or misleading, not merely that the statement is unsubstantiated. Procter & Gamble Co. v. Chesebrough-Pond's, Inc., 747 F.2d 114, 119 (2d Cir. 1984); Sandoz Pharmaceuticals v. Richardson-Vicks,

Inc., 902 F.2d 222, 229 (3d Cir. 1990). Mylan, in its complaint, specifically asserts that the defendants' claims of bioequivalence are unsubstantiated, but nowhere in the complaint does Mylan allege that the drugs are not bioequivalent. Mylan explains this omission by asserting that an affirmative allegation of non-bioequivalence cannot be made because the defendants' records are fraudulent. Mylan, Response Memorandum, at 44. Moreover, Mylan claims that it is "certainly reasonable to infer" a lack of bioequivalence based on the defendants' subsequent actions. Id. With discovery, they claim, they may be able to make this allegation. With regard to Mylan's claims that the commercial advertising conducted on behalf of these drugs was false, Mylan again points to the "strong inference"

that bioequivalence did not exist. Mylan, Response Memorandum, at 45.

A complaint cannot be founded upon inference and what may be proved, given discovery, absent some allegation pled in a complaint which supports the claim and entitles the plaintiff to relief. It stands to reason that this allegation must have more substance than mere inference and possibility. Were this to be the standard, the courts would be deluged by lawsuits, alleging that there was a possibility that some wrong had been done, and that this possibility "might" be susceptible to proof, given sufficient discovery. The Court recognizes that the dismissal of a complaint for failure to state a claim is viewed with disfavor. 5A Wright & Miller, § 1357. Nonetheless, such dismissals must be ordered if there is

insufficient pleading to support the complaint.

In this case, Mylan simply has failed to allege sufficient facts to support its Lanham Act claim. Its complaint, although artfully worded, does not allege that the defendants' drugs were not bioequivalent, and this must be the crux of the Lanham Act violation. If there is bioequivalence, then there is no violation.[15] If there is no

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[15] Mylan points to American Rockwool, Inc. v. Owens-Corning Fiberglass Corp., 640 F. Supp. 1411 (E.D.N.C. 1986), as support for the proposition that a Lanham Act violation may be actionable even if it is partially correct. Id. at 1440. Indeed, that court held that a statement can be literally true and yet so misleading that it can still be actionable under the Lanham Act. Id. citing McNeilab, Inc. v. American Home Products Corp., 501 F. Supp. 517, 524 (S.D.N.Y. 1980). Without analyzing the accuracy of this holding, the Court finds that it is irrelevant to the situation presented in this case. If the defendants' drugs are bioequivalent, then there could be nothing misleading about stating, or implying, that fact. This is all that Mylan claims they have done, and

bioequivalence, then there may be a violation. It is the absence of bioequivalence which calls into question the issue of what Mylan alleges the defendants did or did not imply with their statements. Thus the failure to allege non-bioequivalence is fatal to Mylan's claim.

Mylan may complain that it is inappropriate for its claim to be dismissed at this stage, and that discovery should be allowed to proceed, allowing the Court to make a more informed decision during the summary judgment phase of litigation. Such an argument, however, is as flawed as would be that of the personal injury plaintiff who filed a complaint without alleging an essential element of his or her case, such as injury. Such a complaint could

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therefore no Lanham Act violation would exist.

not withstand a motion to dismiss, nor can the complaint currently under consideration. This Court cannot allow unwarranted inferences to make out an essential element of a claim. See 5A C. Wright and A. Miller, Federal Practice and Procedure: Civil 2d § 1357 at 317 n.18 (1990). Although Mylan "may" be able to make the crucial allegation after discovery, that is not enough.

In this regard, practice on a motion to dismiss differs from that on summary judgment, where inference can supply a link in the chain of circumstantial evidence pointing to the existence of an alleged fact supporting a claim. But if that key fact is never alleged in the first place, the insufficiency of the complaint is patent, and the practice of taking inferences in favor of the party moved against simply has no place.

For the reasons stated above, this Court holds that Mylan has failed to allege any factual support for an essential element of its claim. Accordingly, the defendants' Motion to Dismiss as to Count Three of the Third Amended Complaint will also be granted and an Order to that effect will be entered separately.

Furthermore, as noted in the Court's previous Memorandum and Order of July 8, 1992, this case has languished in the litigation process for years. As the Court observed, "[t]he purpose of litigation is to resolve disputes, not to drag them out endlessly." Mylan, Memorandum and Order, July 8, 1992, at 2. To that end, this Court held that no further motions to amend the pleadings would be entertained. Nothing in this current round of motions has served to change the Court's position. Therefore,

the defendants' various Motions to Dismiss Count Three of Mylan's Third Amended Complaint will be granted with prejudice. This litigation has gone far enough.

CONCLUSION

For the reasons stated above, the various defendants' motions to join pursuant to Fed. R. Civ. P. 12(g) will be granted, as will the defendants' various motions to dismiss Counts One, Two, Three, and Four of the Third Amended Complaint. The motions to dismiss will be granted with prejudice.

/s/ Frederic N. Smalkin
Frederic N. Smalkin
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

MYLAN LABORATORIES, INC.,	:	
Plaintiff	:	
v.	:	CIVIL ACTION NO. S 90-1096
PHARMACEUTICAL BASICS, INC., et al.,	:	
Defendants	:	

ORDER

For the reasons stated in the foregoing Memorandum, IT IS, this 8th day of December, 1992, by the Court, ORDERED:

1. That defendants Matkari's, Pinella's, Par's and Quad's motions to join motions of other defendants BE, and the same hereby ARE, GRANTED;

2. That the defendants' various motions to dismiss the Third Amended Complaint BE, and they hereby ARE, GRANTED;

3. That this case BE, and it hereby IS, DISMISSED as to all defendants and as to all counts, with costs; and

4. That the Clerk of Court mail a copy of the foregoing Memorandum Opinion and of this Order to counsel for the parties and to the pro se defendants.

/s/ Frederic N. Smalkin
Frederic N. Smalkin
United States District Judge

APPENDIX C

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

FILED
November 16, 1993

No. 93-1041
CA-90-1096-S

MYLAN LABORATORIES, INCORPORATED

Plaintiff-Appellant

v.

RAJ MATKARI; DILIP SHAH; RAJU VEGESNA; MOHAMMED F. AZEEM; CHARLES CHANG; DAVID J. BRANCATO; JIN-SHUNG CHANG; WALTER KLETCH; JAN T. STURM; PHARMACEUTICAL BASICS, INCORPORATED; PAR PHARMACEUTICALS, INCORPORATED; QUAD PHARMACEUTICALS,INCORPORATED; AMERICAN THERAPEUTICS,INCORPORATED; AMERICAN HOME PRODUCTSCORPORATION; QUANTUM PHARMICS, LIMITED;STEVEN COLTON; SALVATORE J. PINELLA

Defendants-Appellees

and

ASHOK PATEL; VITARINE PHARMACEUTICALS, INCORPORATED; AKZO, N.V.

Defendants

On Petition for Rehearing with Suggestion for Rehearing In Banc

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The appellees', Par Pharmaceutical, Inc. and Quad Pharmaceuticals, Inc., petition for rehearing and suggestion for rehearing in banc, and American Home Products Corporation and Quantum Pharmics, Limited's petition for rehearing were submitted to this Court. As no member of this Court or the panel requested a poll on the suggestion for rehearing in banc, and

As the panel considered the petitions for rehearing and is of the opinion that they should be denied,

IT IS ORDERED that the petitions for rehearing and suggestion for rehearing in banc are denied.

For the Court,

/s/ Bert M. Montague
CLERK